Nota legal

Donat el caràcter i la finalitat exclusivament docent i eminentment il·lustrativa de les explicacions a classe d'aquesta presentació, l'autor s'acull a l'article 32 de la Llei de propietat intel·lectual vigent respecte de l'ús parcial d'obres alienes com ara imatges, gràfics o altre material contingudes en les diferents diapositives

Totes les imatges presentades s'inclouen com a cites necessàries per il·lustrar les explicacions d'aquesta classe

Título	**Introducción a la Metodología de la investigación clínica**
Fecha	24 de noviembre de 2023
Formato	Presencial
Nº horas presenciales	6
Idioma	Català / Castellano
Entidad organizadora y contacto	Sociedad Catalana de Dolor / Academia de Ciencias Médicas de Cataluña y Baleares

Nº	Hora inicio	Hora fin	Contenido	Docente
1	9:00	9:50	Introducción a la investigación. ¿por qué es necesario investigar?	Sebastià Videla
2	10:00	10:50	Pregunta de la investigación – PICO y pregunta clínica. Justificación del proyecto	Sebastià Videla
	11:00	11:30	Café	
3	11.30	12.20	Tipo de estudios de investigación clínica: diseños. Ensayo clínico, estudios observacionales y proyectos de investigación.	Sebastià Videla
6	12.30	13.20	Estructura de un protocolo. Guías de cómo diseñar la investigación clínica. Estructura de un artículo. Guías de cómo publicar. EQUATOR, CONSORT.	Sebastià Videla
	13:30	14:45	Comida	
7	14:45	15.30	Buenas prácticas clínicas. Responsabilidades de los investigadores	Sebastià Videla
	15:30	16:00	Café	
4	16:00	16:50	Tamaño de la muestra	Cristian Tebé
5	17.00	17.50	Análisis estadístico	Cristian Tebé

- Contingut d'un **protocol** ⇨ Guies de com fer recerca clínica
- Contingut d'un **article** ⇨ Guies de com publicar la recerca clínica ⇨ EQUATOR

Nº	Hora inicio	Hora fin	Contenido	Docente
1	9:00	9:50	Introducción a la investigación. ¿por qué es necesario investigar?	Sebastià Videla
2	10:00	10:50	Pregunta de la investigación – PICO y pregunta clínica. Justificación del proyecto	Sebastià Videla
	11:00	11:30	Café	
3	11.30	12.20	Tipo de estudios de investigación clínica: diseños. Ensayo clínico, estudios observacionales y proyectos de investigación.	Sebastià Videla
6	12.30	13.20	Estructura de un protocolo. Guías de cómo diseñar la investigación clínica. Estructura de un artículo. Guías de cómo publicar. EQUATOR, CONSORT.	Sebastià Videla
	13:30	14:45	Comida	
7	14:45	15.30	Buenas prácticas clínicas. Responsabilidades de los investigadores	Sebastià Videla
	15:30	16:00	Café	
4	16:00	16:50	Tamaño de la muestra	Cristian Tebé
5	17.00	17.50	Análisis estadístico	Cristian Tebé

- a classes anteriors...

- Estructura d'un protocol
- Contingut d'un protocol ⇨ Guies de com fer recerca clínica

“Proceso de investigación”

PROTOCOLO

Trabajo de campo → recogida de la información

Análisis de la información‘ **’statistical analysis plan’**

Comunicación de los resultados

responder a la pregunta

Informe final

>15000 pàgines

Protocol

≈ 60-120 pàgines

oncologia
>120 pàgines

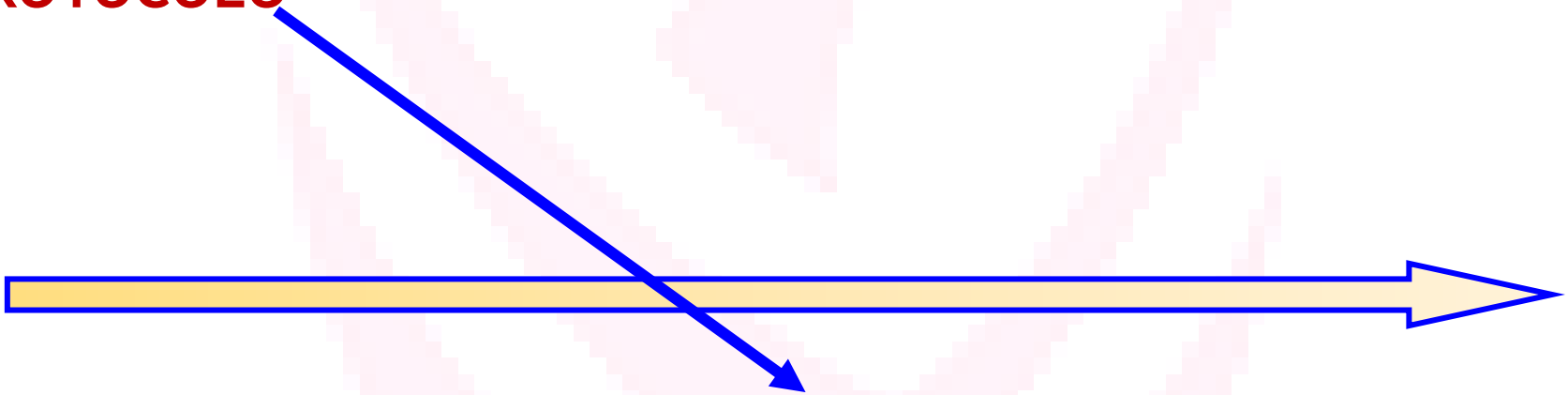
Article

≈ 40 pàgines

https://www.google.es/search?q=matrioskas+originales&rlz=1C1GCEU_esES821ES822&source=lnms&tbm=isch&sa=X&ved=0ahUKEwiV8sKLb_eAhVKJ8AKHcSxB9IQ_AUIDigB&biw=1920&bih=889#imgrc=P3PaeqnQvvPzKM.

“Proceso de investigación”

PROTOCOLO



informe escrito → texto estructurado, documenta, orienta y dirige la ejecución de un proyecto / estudio de investigación

→ describe: **la pregunta**, justificación, hipótesis de trabajo, objetivos, variables, procedimientos…

Guies de com fer recerca clínica

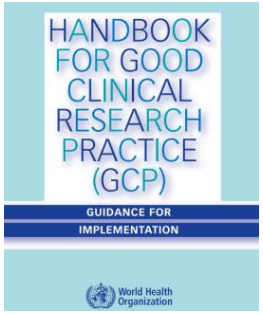
Protocol: estructura

1. **EMA**

   Estructura → ICH: **Guideline for good clinical practice E6(R2)**
   https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-6-r2-guideline-good-clinical-practice-step-5_en.pdf (accedit 2023 03 09)
   → Contingut

2. **OMS**

   https://apps.who.int/iris/bitstream/handle/10665/43392/924159392X_eng.pdf?sequence=1&isAllowed=y (accedit 2023 03 09)



Guies de com fer recerca clínica

International Council for Harmonisation
of Technical Requirements for the
Registration of Pharmaceuticals for Human Use

(Conferencia →) **Consejo Internacional de Armonización**
de requerimientos técnicos para el registro de medicamentos de uso humano

ICH

ICH
harmonisation for better health

Guies de com fer recerca clínica

El **Consejo Internacional de Armonización (ICH)** de requerimientos técnicos para el registro de medicamentos de uso humano

consiste en un **proyecto conjunto** de las

→ **autoridades reguladoras** y

→ la **industria farmacéutica**

procedente de

→ **Europa**,

→ **Estados Unidos** y

→ **Japón**

donde se desarrolla la mayoría de nuevos medicamentos

Guies de com fer recerca clínica

La ICH ⇒ acercamiento de las tres regiones, haciendo posible

→ la identificación de **temas** donde existen **divergencias** que hay que armonizar y
→ el establecimiento de un **método de trabajo común**

⇓

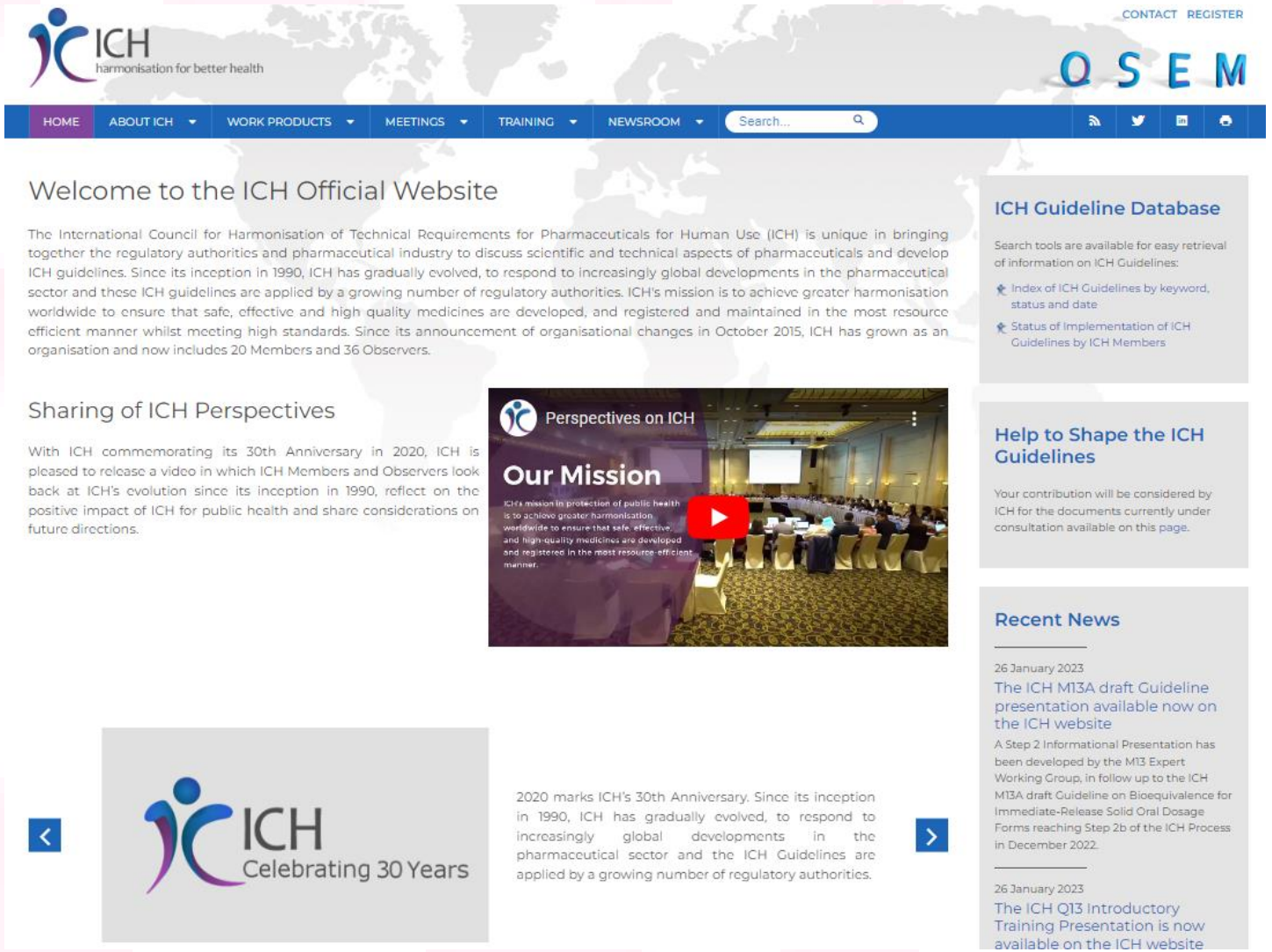
para la elaboración de **recomendaciones** o guías comunes para la industria farmacéutica y las autoridades reguladoras

⇓

promotores de proyectos de investigación clínica

Guies de com fer recerca clínica

http://www.ich.org



(accedit 2023 10 14)

Guies de com fer recerca clínica

Recomendaciones o guías comunes:

- ✓ **CALIDAD (Quality Guidelines)**
- ✓ **SEGURIDAD (Safety Guidelines)**
- ✓ **EFICACIA (Efficacy Guidelines)**
- ✓ **MULTIDISCIPLINARIO (Multidisciplinary Guidelines)**

ICH.

EFFICACY GUIDELINES

- E1 Clinical Safety for Drugs used in Long-Term Treatment
- E2A - E2F Pharmacovigilance
- E3 Clinical Study Reports
- E4 Dose-Response Studies
- E5 Ethnic Factors
- E6 Good Clinical Practice
- E7 Clinical Trials in Geriatric Population
- E8 General Considerations for Clinical Trials
- E9 Statistical Principles for Clinical Trials
- E10 Choice of Control Group in Clinical Trials
- E11 Clinical Trials in Pediatric Population
- E12 Clinical Evaluation by Therapeutic Category
- E14 Clinical Evaluation of QT
- E15 Definitions in Pharmacogenetics / Pharmacogenomics
- E16 Qualification of Genomic Biomarkers
- E17 Multi-Regional Clinical Trials
- E18 Genomic Sampling
- Cross-cutting Topics

ICH. E6: GOOD CLINICAL PRACTICE

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 December 2016
EMA/CHMP/ICH/135/1995
Committee for Human Medicinal Products

Guideline for good clinical practice E6(R2)

Step 5

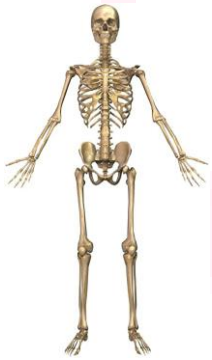
Adopted by CHMP for release for consultation	23 July 2015
Start of public consultation	4 August 2015
End of consultation (deadline for comments)	3 February 2016
Final adoption by CHMP	15 December 2016
Date for coming into effect	14 June 2017

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-6-r2-guideline-good-clinical-practice-step-5_en.pdf (accedit 2023 03 08)

ICH. E6: GOOD CLINICAL PRACTICE

INTRODUCTION

1. GLOSSARY
2. THE PRINCIPLES OF ICH GCP
3. INSTITUTIONAL REVIEW BOARD / INDEPENDENT ETHICS COMMITTEE (IRB/IEC)
4. INVESTIGATOR
5. SPONSOR
6. CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S)
7. INVESTIGATOR'S BROCHURE
8. ESSENTIAL DOCUMENTS FOR THE CONDUCT OF A CLINICAL TRIAL



PROTOCOL AND PROTOCOL AMENDMENT(S)

estructura

E6: GOOD CLINICAL PRACTICE

6. CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S)

6.1 Información General
6.2 Justificación
6.3 Objetivo y Finalidad del Ensayo
6.4 Diseño del Ensayo
6.5 Selección y Retirada de Sujetos
6.6 Tratamiento de los Sujetos
6.7 Valoración de la Eficacia
6.8 Valoración de Seguridad
6.9 Estadística
6.10 Acceso Directo a los Datos/Documentos Fuente
6.11 Control y Garantía de Calidad
6.12 Ética
6.13 Manejo de los Datos y Archivo de los Registros
6.14 Financiación y Seguros
6.15 Política de Publicación
6.16 Nota complementaria

6. CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S)

6.1. General Information

6.1.1.

Protocol title, protocol identifying number, and date. Any amendment(s) should also bear the amendment number(s) and date(s).

6.1.2.

Name and address of the sponsor and monitor (if other than the sponsor).

6.1.3.

Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s) for the sponsor.

6.1.4.

Name, title, address, and telephone number(s) of the sponsor's medical expert (or dentist when appropriate) for the trial.

6.1.5.

Name and title of the investigator(s) who is (are) responsible for conducting the trial, and the address and telephone number(s) of the trial site(s).

6.1.6.

Name, title, address, and telephone number(s) of the qualified physician (or dentist, if applicable), who is responsible for all trial-site related medical (or dental) decisions (if other than investigator).

6.1.7.

Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial.

6. CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S)

6.7. Assessment of Efficacy

6.7.1.

Specification of the efficacy parameters.

6.7.2.

Methods and timing for assessing, recording, and analysing of efficacy parameters.

6.8. Assessment of Safety

6.8.1.

Specification of safety parameters.

6.8.2.

The methods and timing for assessing, recording, and analysing safety parameters.

6.8.3.

Procedures for eliciting reports of and for recording and reporting adverse event and intercurrent illnesses.

6.8.4.

The type and duration of the follow-up of subjects after adverse events.

6. CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S)

MODIFICACIÓN DE UN PROTOCOLO:

Enmienda (Addendum): descripción escrita de una modificación o aclaración formal de un protocolo.

- RELEVANTE
- NO RELEVANTE

Es un documento que se ha de notificar a el/los investigador/es, a el/los CEIC/s, (a las Comunidades Autónomas) y a la agencia reguladora.

6. CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S¿

¿ Cómo se lleva a cabo una enmienda ?

PROTOCOLO DE ENSAYO CLÍNICO

ENSAYO CLÍNICO DE FASE II, PRUEBA DE CONCEPTO, CON ASIGNACIÓN ALEATORIA, ABIERTO Y MULTICÉNTRICO, PARA EVALUAR LA EFICACIA Y SEGURIDAD DE ICATIBANT EN PACIENTES INFECTADOS POR SARS-COV-2 (COVID-19) E INGRESADOS EN UNIDADES DE HOSPITALIZACIÓN, SIN VENTILACIÓN MECÁNICA INVASIVA, COMPARADO CON EL ESTANDAR DE CUIDADO (ICAT-COVID)

Producto experimental: Icatibant (Firazyr®)

Promotor:
Instituto de Investigación Biomédica de Bellvitge (IDIBELL)
Avinguda de la Granvia de l'Hospitalet, 199
08908-L'Hospitalet de Llobregat, Barcelona

Código de Protocolo: HUB-MdI-ICAT-COVID-201
Código EudraCT: 2020-002166-13
Fase de desarrollo: II

Investigador Coordinador:
Dr. Pierre Malchair
Servicio de Urgencias
Hospital Universitario de Bellvitge
Carrer de la Feixa Llarga, s/n,
08907-L'Hospitalet de Llobregat, Barcelona
Tel.: +34. 93 2607575

Monitor Médico:
Dr. Jordi GIOL Amich / Dr. Xavier SOLANICH Moreno
Servicio de Urgencias
Servicio de Medicina Interna
Hospital Universitario de Bellvitge
Carrer de la Feixa Llarga, s/n,
08907-L'Hospitalet de Llobregat, Barcelona
Tel.: +34. 93 2607575

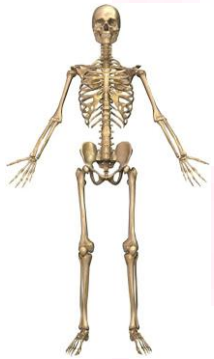
Versión protocolo	Fecha
Versión 2.0	15/05/2020 - versión evaluada por CEIm.
Versión 3.0	05/06/2020 - incluye las aclaraciones del CEIm y la AEMPS.
Versión 3.1	11/12/2020 – se incluye el cambio de promotor, investigador coordinador y monitor médico, se actualiza el equipo del promotor, se actualiza el protocolo de acuerdo con las evidencias actuales (diciembre 2020) y se incluye un nuevo centro.
Versión 3.2	21/01/2021 – se corrigen las discrepancias detectadas entre el resumen y el cuerpo del protocolo. Incluye la aportación económica que realizará el laboratorio TAKEDA.

Versión 3.2 del 21 de enero de 2021

Cambios realizados en el protocolo de la versión 3.2 respecto a la versión previa (versión 3.1)	
Página	**Se introduce la siguiente modificación:**
9, 30	se unifica el primer criterio de exclusión en el resumen y cuerpo del protocolo, quedando: "Muerte inminente (expectativa de vida ≤ a 24h)."
20	Mención al aporte económico que será realizado por el laboratorio TAKEDA para cada centro, destinado a la subsanación de costes propios del estudio.

Cambios realizados en el protocolo de la versión 3.1 respecto a la versión previa (versión 3.0)	
Página	**Se introduce la siguiente modificación:**
1, 21, 63	se introduce el cambio de promotor, de investigador coordinador y de monitor médico.
7, 29-30	El protocolo se actualiza de acuerdo con las evidencias actuales (diciembre 2020): se incluye dexametasona y remdesivir en la medicación del SoC.
7, 9, 31, 39, 44	El protocolo se actualiza de acuerdo con las evidencias actuales (diciembre 2020): Se incluye la prueba de antígeno como prueba diagnóstica de la infección por SARS-CoV-2. Por tanto, la infección por SARS-CoV-2 se confirmará por PCR o antígeno
9, 31	El protocolo se actualiza de acuerdo con las evidencias actuales (diciembre 2020): Se modifica de 4 a 10 días desde la confirmación de la infección por SARS-CoV-2 para ser incluido en el ensayo clínico: "Criterio de inclusión: Infección por SARS-CoV-2 confirmada por PCR o antígeno ≤10 días antes de la aleatorización"
9, 31	El protocolo se actualiza de acuerdo con las evidencias actuales (diciembre 2020): se incluye como criterio de exclusión: "Haber sido vacunado contra el SARS-CoV-2 / contra el COVID"
30, 61	Se incluye un nuevo centro participante.
61	Se incluye el nuevo investigador principal del Hospital Universitario de Bellvitge. Se actualiza el equipo del promotor.

Cambios realizados en el protocolo de la versión 3.0 respecto a la versión previa (versión 2.0)	
Página	**Se introduce la siguiente modificación:**
1, 4, 5, 63, 67	en el título, se ha añadido la palabra "invasiva" para especificar el tipo de ventilación mecánica que queda excluida del estudio.
6, 27	se añade el apartado 7.2 Objetivos secundarios: Objetivo exploratorio: Evaluar el impacto de icatibant en la carga viral del SARS-CoV-2.
7, 39	se ha identificado la escala de estado clínico de la OMS como la escala de 8 puntos.
8, 40, 41, 44	se añaden las 3 visitas que se realizarán durante el periodo de hospitalización: visita 2, visita 3 y



PROTOCOL AND PROTOCOL AMENDMENT(S)

estructura

contingut

https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/clinical-efficacy-safety-guidelines

https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/clinical-efficacy-safety-guidelines

Paediatric medicines

Pharmacovigilance

PRIME: priority medicines

Quality by design

Scientific advice and protocol assistance

Scientific guidelines

Search guidelines

Biologicals

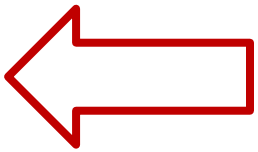
Clinical efficacy and safety

Alimentary tract and metabolism

Blood and blood-forming organs

Clinical efficacy and **safety guidelines** are provided for:

- Alimentary tract and metabolism
- Blood and blood forming organs
- Blood products (including biotechnological alternatives)
- Cardiovascular system
- Dermatologicals
- Genito-urinary system and sex hormones
- Anti-infectives for systemic use
- Antineoplastic and immunomodulating agents
- Rheumatology/musculoskeletal system
- Nervous system
- Respiratory system
- Radiopharmaceuticals and diagnostic agents
- Allergy/Immunology
- Biostatistics
- General



Topics

- Guidance
- Scientific guidelines

https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/clinical-efficacy-safety/clinical-efficacy-safety-nervous-system

Adaptive pathways

Advanced therapies

Clinical trials

Compassionate use

Compliance

Data on medicines (ISO IDMP standards)

Ethical use of animals

Innovation in medicines

Medicines for older people

Orphan designation

Paediatric medicines

Pharmacovigilance

PRIME: priority medicines

Quality by design

Scientific advice and protocol assistance

Scientific guidelines

Search guidelines

Clinical efficacy and safety: nervous system

The European Medicines Agency's scientific guidelines on the clinical evaluation of medicines used in nervous-system disorders help medicine developers prepare marketing authorisation applications for human medicines.

For a complete list of scientific guidelines currently open for consultation, see Public consultations.

Guidelines

- Clinical development of medicinal products for the treatment of autism spectrum disorder (ASD) - Scientific guideline
- Clinical development of medicinal products intended for the treatment of pain - Scientific guideline
- Clinical investigation of medicinal products for the treatment and prevention of bipolar disorder - Scientific guideline
- Clinical investigation of medicinal products for the treatment of amyotrophic lateral sclerosis - Scientific guideline
- Clinical investigation of medicinal products for the treatment of attention deficit hyperactivity disorder (ADHD) - Scientific guideline
- Clinical investigation of medicinal products for the treatment of Duchenne and Becker muscular dystrophy - Scientific guideline
- Clinical investigation of medicinal products for the treatment of multiple sclerosis - Scientific guideline
- Clinical investigation of medicinal products for the treatment of obsessive compulsive disorder - Scientific guideline
- Clinical investigation of medicinal products for treatment of migraine - Scientific guideline
- Clinical investigation of medicinal products in the treatment of depression - Scientific guideline
- Clinical investigation of medicinal products in the treatment of epileptic disorders - Scientific guideline
- Clinical investigation of medicinal products in the treatment of Parkinson's disease - Scientific guideline
- Clinical investigation of medicinal products indicated for generalised anxiety disorder - Scientific guideline

https://www.ema.europa.eu/en/clinical-development-medicinal-products-intended-treatment-pain-scientific-guideline

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 December 2016
EMA/CHMP/970057/2011
Committee for Medicinal Products for Human Use (CHMP)

Guideline on the clinical development of medicinal products intended for the treatment of pain

Draft Agreed by Biostatistics Working Party	December 2012
Draft Agreed by Paediatric Committee	March 2013
Draft Agreed by Central Nervous System Working Party	May 2013
Adoption by CHMP for release for consultation	30 May 2013
Start of public consultation	1 June 2013
End of consultation (deadline for comments)	30 November 2013
Draft Agreed by Central Nervous System Working Party	October 2015
Adoption by CHMP for release for 2nd consultation	17 December 2015
Start of public consultation	21 December 2015
End of consultation (deadline for comments)	31 March 2016
Agreed by Central Nervous System Working Party	2 December 2016
Adopted by CHMP	15 December 2016
Date of coming into effect	1 July 2017

This guideline replaces guidelines CPMP/EWP/252/03 Rev. 1 and CPMP/EWP/612/00

Keywords	***pain, neuropathic, nociceptive, chronic, acute, analgesia, mild, moderate, guideline, medicinal products***

Guideline on the clinical development of medicinal products intended for the treatment of pain

Table of contents

5.2. Clinical Efficacy

5.2.1. Methods to assess efficacy

Pain Measurement:

There are a number of scales to assess pain but none of them is completely free of limitations.

As pain is always subjective, self-assessment scales provide the most valid measure of the experience. At present no validated objective measures are available that would be feasible in clinical trials. Pain intensity (PI) is still the key measure of efficacy of an analgesic drug and should always be reported. Among the pain rating scales the Visual analogue scale (VAS), numeric rating scale (NRS) and verbal rating scale (VRS) have been extensively used and validated[13].

The VAS is a continuous variable on a 10 cm line representing "no pain" to "worst imaginable pain", whereas the NRS is a discrete variable describing pain level with numbers from 0 to 10. Due to practical considerations the latter is the most commonly used scale. The VRS, consisting of a series of verbal pain descriptors, has been shown to lack sensitivity to detect changes in PI when compared with VAS or NRS.

The main shortcoming of the single-item pain rating scales is that they do not cover the whole range of pain qualities. Therefore multidimensional outcome measures are recommended to be used in addition, especially for trials in chronic pain. Multidimensional assessment tools have been developed to assess not only pain intensity, but also sensory and affective qualities of pain. They may reveal differential effects of treatments on different pain components. The McGill Pain Questionnaire (MPQ, SF-MPQ) is the one most frequently used in chronic pain and has been demonstrated to be a reliable and valid measurement tool. The Neuropathic Pain Scale (NPS) and Neuropathic Pain Symptom Inventory (NPSI) have been specifically developed and validated for the evaluation of neuropathic pain[15] and are recommended for the evaluation of treatment effects on neuropathic symptoms. Validated disease-specific pain measurement tools are preferred.

Measurement of physical functioning:

As chronic pain interferes with daily activities, additional patient reported outcome measures (PROs) of physical functioning are recommended[16] as secondary endpoints. They typically assess multiple aspects of function, including activities of daily living. Disease specific measures (e.g. Oswestry Disability Index for low back pain, WOMAC osteoarthritis index) have not been developed for many chronic pain conditions and the results are not applicable more broadly to other pain conditions. New disease specific measures of physical function may be considered if supportive independent validation is provided. More general Health-related quality of life (HRQOL) tools assess patient's perception of the impact of disease and treatment on daily life, physical, psychological and social functioning and well-being. The Multidimensional Pain Inventory (MPI) and the Brief Pain Inventory (BPI) both provide reliable and valid measures in diverse chronic pain conditions. The SF-36 Health Survey is the most commonly used generic measure of HRQOL and has been used in numerous clinical trials of diverse medical and psychiatric disorders. EQ-5D is also a common generic measure of HRQOL.

Measurement of emotional functioning:

Co-morbid anxiety and depression are common in patients with chronic pain. Mood changes, anxiety and sleep disturbance may change pain perception and hence may affect efficacy assessments. The pharmacodynamic effects of an investigational treatment may directly influence these comorbidities. The impact of such factors on the observed measures of pain should be evaluated where appropriate. Thus, a basal psychological and psychosocial evaluation with appropriate measures (e.g. BDI, POMS, HADS, MOS-SS) is strongly recommended for clinical trials in chronic pain.

Measurement of Global Improvement and satisfaction with treatment:

The Global Impression of Change reported by the patient (PGIC) may be a useful supportive general indicator of the overall perceived benefit of treatment in chronic pain trials[15,16].

6.1. Acute Pain

Table 1: Examples of pain models appropriate to be used in efficacy studies in acute pain

Pain Intensity		mild to moderate (in general NRS ≤ 6, VAS ≤ 60 mm)	Moderate to severe (in general NRS ≥4, VAS ≥ 40 mm)
Pain Model	Somatic pain	Tooth extraction Minor cutaneous surgery	Surgical removal of impacted 8th teeth Bunionectomy Major orthopedic surgery Major skeletal trauma Dressing changes in burns pain
	Visceral pain	Primary dysmenorrhea	Acute pancreatitis Renal / biliary colic
	Both somatic and visceral pain	Minimally invasive (laparoscopic) abdominal/gynecological surgery	Abdominal / thoracic surgery

6.2.3. Neuropathic Pain

Neuropathic pain is frequently resistant to treatment and if an effect is observed it may be transient. Non-steroidal anti-inflammatory drugs are generally ineffective. A number of medicinal products have approved indications for neuropathic pain but have variable efficacy, including anticonvulsants (gabapentinoids, carbamazepine), tricyclic antidepressants, SNRIs, topically applied lidocaine and capsaicin. The following general principles can be stated for the data requirements to support different types in indications in neuropathic pain:

- If only a single pain model is studied the approvable indication will normally be limited to the specific condition studied (e.g. trigeminal neuralgia).
- If models of just central neuropathic pain or of just peripheral neuropathic pain are studied, the indication will normally be restricted accordingly. If this is the objective of clinical development, efficacy should be shown in two or more models of central or peripheral neuropathic pain, as applicable.
- To justify a general indication for the treatment of neuropathic pain, efficacy needs to be demonstrated independently in both central and peripheral neuropathic pain. Efficacy should be shown in two or more models of peripheral neuropathic pain. Data in a single model of central neuropathic pain could be sufficient in this situation to support the broader indication.

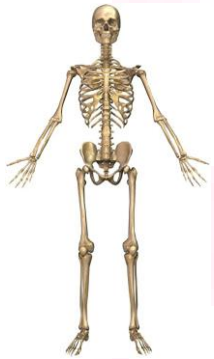
Well established central neuropathic models include spinal cord injury and post-stroke thalamic pain. Well established peripheral neuropathic models include post herpetic neuralgia, diabetic painful

6.2.5. Efficacy studies in chronic pain

Efficacy studies in chronic pain should be performed according to the general considerations for confirmatory trials (see section 5.2.4).

Patient population

Patients included in chronic pain trials should generally have exhibited symptoms for more than 3 months with no substantial recent change in pain severity or clinical management. Clinical evaluation inclusion criteria in chronic pain trials should include the duration of pain, stability of symptoms before enrolment and pain medication history. All of these aspects should be documented for each patient. Patients' pain at baseline should be categorised according to relative contributions of nociceptive and neuropathic components, including their duration, quality and location. Screening tools may help to identify patients with a neuropathic pain component (e.g. Pain DETECT, LANSS- Pain Scale, NPQ, DN4)[15]. The location and/or distribution of underlying pathology should be characterised as far as possible. Where relevant a survey of the distribution of pain (e.g. patient pain drawing) is encouraged; a comparison with known anatomical aspects may provide valuable information on neuropathic features. Any associated negative and positive phenomena (sensory findings) should be described.



PROTOCOL AND PROTOCOL AMENDMENT(S)

estructura

contingut

Nº	Hora inicio	Hora fin	Contenido	Docente
1	9:00	9:50	Introducción a la investigación. ¿por qué es necesario investigar?	Sebastià Videla
2	10:00	10:50	Pregunta de la investigación – PICO y pregunta clínica. Justificación del proyecto	Sebastià Videla
	11:00	11:30	Café	
3	11.30	12.20	Tipo de estudios de investigación clínica: diseños. Ensayo clínico, estudios observacionales y proyectos de investigación.	Sebastià Videla
6	12.30	13.20	Estructura de un protocolo. Guías de cómo diseñar la investigación clínica. Estructura de un artículo. Guías de cómo publicar. EQUATOR, CONSORT.	Sebastià Videla
	13:30	14:45	Comida	
7	14:45	15.30	Buenas prácticas clínicas. Responsabilidades de los investigadores	Sebastià Videla
	15:30	16:00	Café	
4	16:00	16:50	Tamaño de la muestra	Cristian Tebé
5	17.00	17.50	Análisis estadístico	Cristian Tebé

- Contingut d'un **protocol** ⇨ Guies de com fer recerca clínica
- Contingut d'un **article** ⇨ Guies de com publicar la recerca clínica ⇨ EQUATOR

Informe final

>15000 pàgines

Protocol

≈ 60-120 pàgines

oncologia

>120 pàgines

Mètodes

Resultats

Article

≈ 40 pàgines

https://www.google.es/search?q=matrioskas+originales&rlz=1C1GCEU_esES821ES822&source=lnms&tbm=isch&sa=X&ved=0ahUKEwiV8sKLb_eAhVKJ8AKHcSxB9IQ_AUIDigB&biw=1920&bih=889#imgrc=P3PaeqnQvvPzKM.

- a classes anteriors...
- Estructura d'un article

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- Contingut d'un article ⇨ EQUATOR

- a classes anteriors...

- Estructura d'un article

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- Contingut d'un article ⇨ EQUATOR

“Proceso de investigación”

PROTOCOLO → Trabajo de campo → recogida de la información → Análisis de la información‘ **’statistical analysis plan’** → Comunicación de los resultados

responder a la pregunta

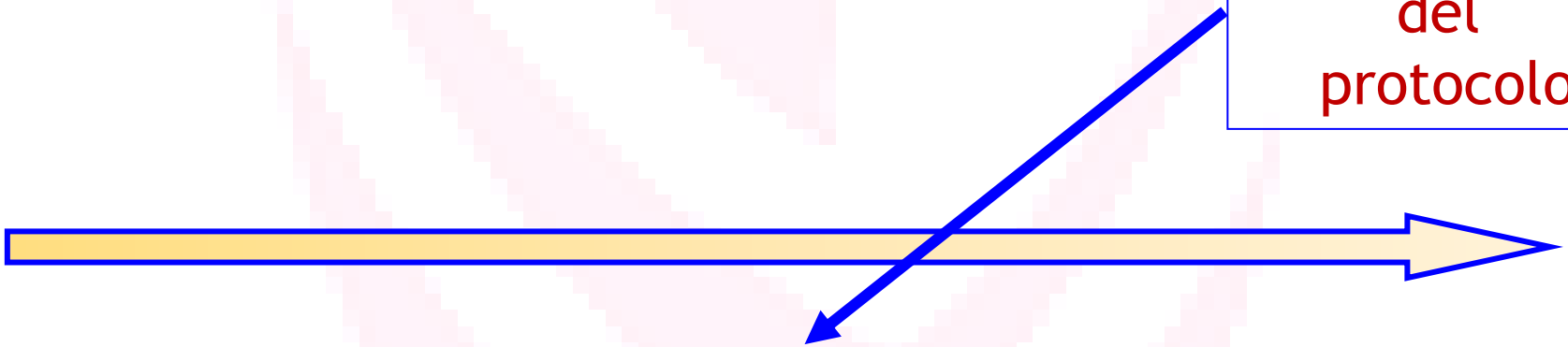
http://www.economiadelasalud.com/Ediciones/03/03Images/03EnPortadaPrescripcion.jpg

“Proceso de investigación”

Els protocols de recerca clínica es poden publicar

PROTOCOLO

Comunicación del protocolo



artículo científico

informe escrito → texto estructurado, que describe resultados originales de una investigación, de ideas o debates y que se va a **publicar en una revista científica** (“peer review” / “revisión por pares”)

- a classes anteriors...
- Estructura d'un article

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Estructura de un artículo científico

→ Puede variar dependiendo de la revista (‘normas de publicación de la revista’)

Estructura ‘genérica’ de un artículo científico

- Página del Título (‘title page’)
- Contenido (cuerpo del artículo):

Estructura de un artículo científico

- Página del Título ('title page')

  → **Título**

  → título corto / consecutivo ("Running title")

  → Autoría / autores

  → Filiación de cada autor

  → Autor de correspondencia

  → Atribuciones de autoría ("Authorship attributions")

  → Financiación

  → Conflictos de interés ("Conflicts of Interest")

  → Agradecimientos

Estructura ‘genérica’ de un artículo científico

- Página del Título (‘title page’)

- Contenido (cuerpo del artículo):
  - → Resumen (“Abstract”): limitación de palabras
  - → Palabras clave (“keywords”)

MeSH (Medical Subject Headings) descriptores en ciencias de la salud

  - → **Introducción**
  - → Pacientes (Materiales) y **métodos**
  - → **Resultados**
  - → **Discusión**

  - → **Bibliografía / referencias bibliográficas**

- a classes anteriors...

- Estructura d'un article

  ↕

- Contingut d'un article

  ⇨ EQUATOR

  ⇨ Guies de publicació ⇨ CONSORT

International Committee of Medical Journal Editors

Ante un problema 'médico'

⇓

Recurrimos a la literatura de la
investigación biomédica
en busca de pruebas ('evidencias')

⇓

Los resultados de la investigación biomédica influyen en el tratamiento / prevención de las enfermedades.

historia. Normativas para publicación

International Committee of Medical Journal Editors

’80, ¿ Cuál es el Valor / Importancia que tienen los resultados en la toma de decisiones ?

’80-’90, deficiencias metodológicas en **cómo** se publica

afectaba a

- todas las especialidades médicas, y
- todos los diseños

International Committee of Medical Journal Editors

’80, ¿ Cuál es el Valor / Importancia que tienen los resultados en la toma de decisiones ?

’80-’90, deficiencias metodológicas en cómo se publica

afectaba a

- todas las especialidades médicas, y
- todos los diseños

Influencia negativa en las decisiones médicas

historia. Normativas para publicación

International Committee of Medical Journal Editors

’80, ¿ Cuál es el Valor / Importancia que tienen los resultados en la toma de decisiones ?

’80-’90, deficiencias metodológicas en cómo se publica

⇩

afectaba a

- todas las especialidades médicas, y
- todos los diseños

➔ Normativas para publicación

historia. Normativas para publicación

Directrices de consenso que recogen puntos específicos / "puntos críticos" sobre la información que deben aportar los autores de sus estudios.

Objetivos:

INVESTIGADOR: presentación clara / transparente de la investigación realizada

REVISORES / EDITORES: conocer los puntos débiles para

- evitar su publicación o
- mejorar la publicación

LECTORES: fiabilidad y relevancia resultados

¿ Cuántas directrices de publicación existen ?

⇒ Tantas como diseños de estudios

https://www.equator-network.org/

March 2006 → EQUATOR programme

equator network

Enhancing the QUAlity and Transparency Of health Research

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Your one-stop-shop for writing and publishing high-impact health research

find reporting guidelines | improve your writing | join our courses | run your own training course | enhance your peer review | implement guidelines

Library for health research reporting

The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.

- Search for reporting guidelines
- Not sure which reporting guideline to use?
- Reporting guidelines under development
- Visit the library for more resources

Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Study protocols	SPIRIT	PRISMA-P
Diagnostic/prognostic studies	STARD	TRIPOD
Case reports	CARE	Extensions
Clinical practice guidelines	AGREE	RIGHT
Qualitative research	SRQR	COREQ
Animal pre-clinical studies	ARRIVE	
Quality improvement studies	SQUIRE	Extensions
Economic evaluations	CHEERS	

See all 588 reporting guidelines

Accedit 15 octubre 2023

https://www.equator-network.org/

Relevant more generic / specialised reporting guidelines (i.e. main generic guideline or extension to a generic guideline)	Specialised

CONSORT Harms: Junqueira DR, Zorzela L, Golder S, Loke Y, Gagnier JJ, Julious SA, Li T, Mayo-Wilson E, Pham B, Phillips R, Santaguida P, Scherer RW, Gøtzsche PC, Moher D, Ioannidis JPA, Vohra S; CONSORT Harms Group. CONSORT Harms 2022 statement, explanation, and elaboration: updated guideline for the reporting of harms in randomized trials.
BMJ. 2023;381:e073725. PMID: 37094878
J Clin Epidemiol. 2023:S0895-4356(23)00090-2. PMID: 37100738

CONSORT Non-inferiority: Piaggio G, Elbourne DR, Pocock SJ, Evans SJW, Altman DG, for the CONSORT Group. Reporting of noninferiority and equivalence randomized trials. Extension of the CONSORT 2010 statement. JAMA. 2012; 308(24): 2594-2604. PMID: 23268518

CONSORT Cluster: Campbell MK, Piaggio G, Elbourne DR, Altman DG; CONSORT Group. Consort 2010 statement: extension to cluster randomised trials. BMJ. 2012;345:e5661. PMID: 22951546

CONSORT Herbal: Gagnier JJ, Boon H, Rochon P, Moher D, Barnes J, Bombardier C, for the CONSORT Group. Reporting randomized, controlled trials of herbal interventions: an elaborated CONSORT Statement. Ann Intern Med. 2006;144(5):364-367. PMID: 16520478

CONSORT Non-pharmacological treatment interventions: Boutron I, Altman DG, Moher D, Schulz KF, Ravaud P; CONSORT NPT Group. CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts. Ann Intern Med. 2017;167(1):40-47. PMID: 28630973

CONSORT Abstracts: Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, Schulz KF, the CONSORT Group. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med. 2008; 5(1):e20. PMID: 18215107

Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, Schulz KF, the CONSORT Group. CONSORT for reporting randomised trials in journal and conference abstracts. Lancet. 2008;371(9609):281-3. PMID: 18221781

CONSORT Pragmatic Trials: Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, Oxman AD, Moher D; CONSORT group; Pragmatic Trials in Healthcare (Practihc) group. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ. 2008;337:a2390. PMID: 19001484

STRICTA Controlled trials of acupuncture: MacPherson H, Altman DG, Hammerschlag R, Youping L, Taixiang W, White A, Moher D; STRICTA Revision Group. Revised STandards for Reporting Interventions in Clinical Trials of

Accedit 15 octubre 2023


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  ⇨ Guies de publicació ⇨ CONSORT

http://www.consort-statement.org/

CONSORT – **CON**solidated **S**tandards **O**f **R**eporting **T**rials

CONSORT TRANSPARENT REPORTING of TRIALS

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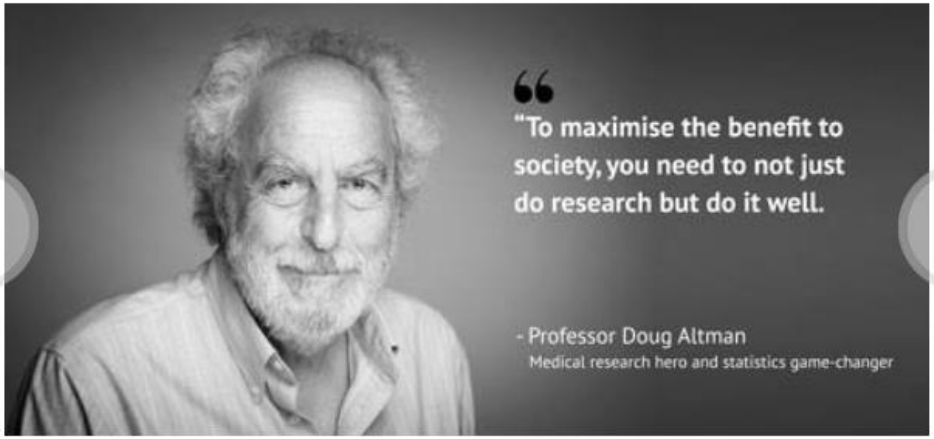

Welcome to the CONSORT Website

CONSORT stands for Consolidated Standards of Reporting Trials and encompasses various initiatives developed by the CONSORT Group to alleviate the problems arising

CONSORT 2010 Key Documents

- CONSORT 2010 Checklist
- CONSORT 2010 Flow Diagram
- CONSORT 2010 Statement
- CONSORT 2010 Explanation and Elaboration Document

http://www.consort-statement.org/

CONSORT – **CON**solidated **S**tandards **O**f **R**eporting **T**rials

1993: 30 experts comprised of medical journal editors, clinical trialists, epidemiologists, and methodologists met in Ottawa, Canada with the aim of developing a new scale to assess the quality of randomized controlled trial (RCT) reports.

1996: 1st CONSORT statement

2001: updated

2010: updated ("evolving guideline")

The CONSORT statement

The main product of CONSORT is the CONSORT Statement, which is an evidence-based, **minimum set of recommendations** for reporting randomized trials. It offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation.

The CONSORT Statement comprises a **25-item checklist** and a **flow diagram**. The checklist items focus on reporting how the trial was designed, analyzed, and interpreted; the flow diagram displays the progress of all participants through the trial.

http://www.consort-statement.org/

ELSEVIER

Journal of Clinical Epidemiology 63 (2010) e1–e37

Journal of Clinical Epidemiology

ORIGINAL ARTICLE

CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials

David Moher[a,*], Sally Hopewell[b], Kenneth F. Schulz[c], Victor Montori[d], Peter C. Gøtzsche[e], P.J. Devereaux[f], Diana Elbourne[g], Matthias Egger[h], Douglas G. Altman[b]

[a]*Ottawa Methods Centre, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa Hospital, Ottawa, Ontario, Canada, K1H 8L6*
[b]*Centre for Statistics in Medicine, University of Oxford, Wolfson College, Oxford*
[c]*Family Health International, Research Triangle Park, NC 27709, USA*
[d]*UK Knowledge and Encounter Research Unit, Mayo Clinic, Rochester, MN, USA*
[e]*The Nordic Cochrane Centre, Rigshospitalet, Blegdamsvej 9, Copenhagen, Denmark*
[f]*McMaster University Health Sciences Centre, Hamilton, Canada*
[g]*Medical Statistics Unit, London School of Hygiene and Tropical Medicine, London*
[h]*Institute of Social and Preventive Medicine (ISPM), University of Bern, Switzerland*

Accepted 8 February 2010

http://www.consort-statement.org/

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Journal of Clinical Epidemiology 63 (2010) 834–840

Journal of Clinical Epidemiology

ORIGINAL ARTICLES

CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials

Kenneth F. Schulz[a,*], Douglas G. Altman[b], David Moher[c]
for the CONSORT Group

[a]*Family Health International, Research Triangle Park, NC 27709, USA*
[b]*Centre for Statistics in Medicine, University of Oxford, Wolfson College, Oxford*
[c]*Ottawa Methods Centre, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Department of Epidemiology and Community Medicine, University of Ottawa, Ottawa, Canada*

Accepted 9 December 2009

http://www.consort-statement.org/

Med Clin (Barc). 2011;137(5):213–215

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MEDICINA CLINICA

www.elsevier.es/medicinaclinica

Artículo especial

Declaración CONSORT 2010: actualización de la lista de comprobación para informar ensayos clínicos aleatorizados de grupos paralelos

CONSORT 2010 Declaration: Updated guideline for reporting parallel group randomised trials

Albert Cobos-Carbó [a,*] y Federico Augustovski [b]

[a] *Unidad de Bioestadística, Departamento de Salud Pública, Facultad de Medicina, Universidad de Barcelona, Barcelona, España*
[b] *Instituto de Efectividad Clínica y Sanitaria (IECS). Servicio de Medicina Familiar y Comunitaria, Hospital Italiano de Buenos Aires, Argentina*

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4,5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	no changes happened
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9,10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	no changes happened
Sample size	7a	How sample size was determined	10,11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	non applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	---

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10,11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	12
	14b	Why the trial ended or was stopped	11
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Figure 3, table 2 and 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	13
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	13
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	13,14
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	15,16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	16,17
Other information			
Registration	23	Registration number and name of trial registry	3,6
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2,18

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010. Lista de comprobación

- **Título y resumen:** **sección 1** (4%)
- **Introducción:** **sección 2** (4%)
- **Métodos:** **sección 3 - 12** (40%)
- **Resultados:** **sección 13 - 19** (28%)
- **Discusión:** **sección 20 - 22** (12%)
- **Otra información:** **sección 23 - 25** (12%)

- a classes anteriors...

- Estructura d'un article

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- Contingut d'un article

  ⇨ EQUATOR

  ⇨ Guies de publicació ⇨ CONSORT: llista de Verificació

CONSORT 2010. Título y resumen: sección 1

Titulo y resumen		
	1a	Identificado como un ensayo aleatorizado en el ti
	1b	

Fácil identificación en las bases de datos

Title example:
"Smoking reduction with oral nicotine inhalers: double blind, **randomised** clinical trial of efficacy and safety"
[Bolliger, et al. BMJ 2000;321:329e33.].

CONSORT 2010.

Título y resumen: sección 1

Titulo y resumen		
	1a	Identificado como un ensayo aleatorizado en el titulo
	1b	Resumen estructurado del diseño, métodos, resultados y conclusiones del ensayo (para una orientación específica, véase CONSORT for abstracts)

CONSORT 2010. Introducción: sección 2

Introducción		
Antecedentes y Objetivos	2a	Antecedentes científicos y justificación
	2b	Objetivos específicos o hipótesis

Protocolo

⇓

Actualización bibliográfica !

CONSORT 2010. Métodos: sección 3 - 12

Métodos		
Diseño del estudio	3a	Descripción del diseño del ensayo (por ejemplo, paralelo, factorial), incluida la razón de asignación

"This was a multicenter, stratified (6 to 11 years and 12 to 17 years of age, with imbalanced randomisation [2:1]), double-blind, placebo-controlled, parallel-group study conducted in the United States (41 sites)"

[Blumer et al. Pediatrics 2009;123:e770e6]

CONSORT 2010. Métodos: sección 3 - 12

Métodos		
Diseño del estudio	3a	Descripción del diseño del ensayo (por ejemplo, paralelo, factorial), incluida la razón de asignación
	3b	Cambios importantes en los métodos después de iniciar el ensayo (por ejemplo, criterios de selección) y su
Participantes	4a	
	4b	
Intervenciones	5	

Enmiendas al protocolo

CONSORT 2010.

Métodos: sección 3 - 12

Métodos		
Diseño del estudio	3a	Descripción del diseño del ensayo (por ejemplo, paralelo, factorial), incluida la razón de asignación
	3b	Cambios importantes en los métodos después de iniciar el ensayo (por ejemplo, criterios de selección) y su justificación
Participantes	4a	Criterios de selección de los participantes
	4b	Procedencia (centros e instituciones) en que se registraron los datos
Intervenciones	5	

Validez externa

Métodos: sección 3 - 12

Randomized patients (in a 1:1 ratio) received the combination-therapy of 10 mg of daptomycin intravenously per kilogram of body weight daily plus 2 g of fosfomycin intravenously each 6 hours (experimental group) or the mono-therapy of 10 mg of daptomycin intravenously per kilogram of body weight daily (control group).

Daptomycin was administered intravenously a 30-minute infusion once a day, and fosfomycin was administered intravenously a 60-minute infusion each 6 hours. The duration of therapy was determined by the investigator on the basis of the working diagnosis. If the bacteremia was not complicated, the treatment duration was of the 10-14 days; if the bacteremia was complicated the treatment duration was of the 28-42 days.

CONSORT 2010. Métodos: sección 3 - 12

Métodos		
Resultados	6a	Especificación *a priori* de las variables respuesta (o desenlace) principal(es) y

Primary endpoint: > Importancia → Cálculo del tamaño de la muestra

Treatment success / responders

"The primary endpoint with respect to efficacy in psoriasis was the **proportion of patients** achieving a 75% improvement in psoriasis activity from baseline to 12 weeks as measured by the PASI [psoriasis area and severity index]".

[Mease et al. Lancet 2000;356:385e90]

Métodos: sección 3 - 12

Métodos		
Resultados	6a	Especificación a priori de las variables respuesta (o desenlace) principal(es) y secundarias, incluidos cómo y cuándo se evaluaron
	6b	Cualquier cambio en las variables respuesta tras el inicio del ensayo, junto con los motivos de la(s) modificación(es)
Tamaño de la muestra	7a	
	7b	

CONSORT 2010.

Métodos: sección 3 - 12

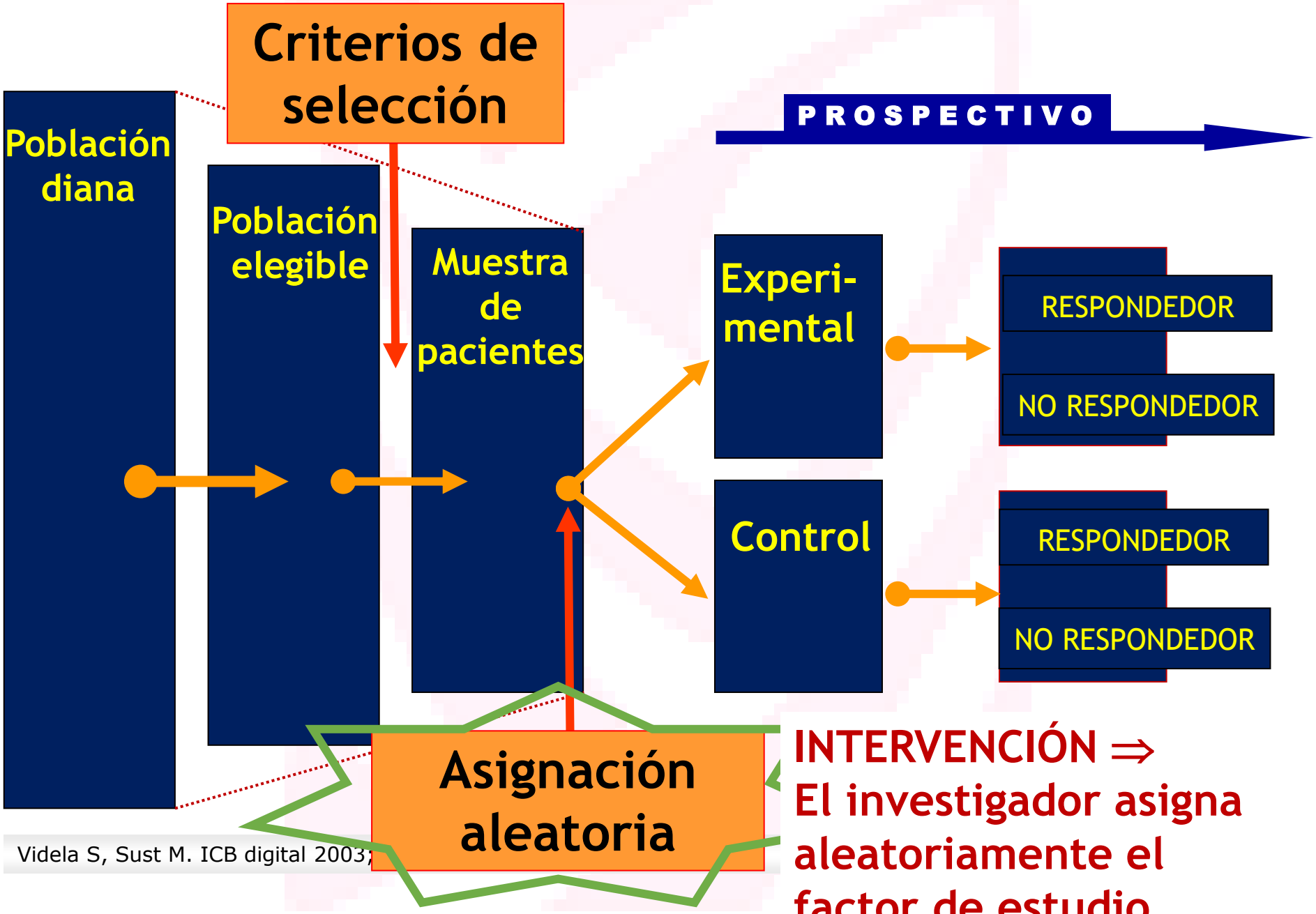
Métodos		
Resultados	6a	Especificación a priori de las variables respuesta (o desenlace) principal(es) y secundarias, incluidos cómo y cuándo se evaluaron
	6b	Cualquier cambio en las variables respuesta tras el inicio del ensayo, junto con los motivos de la(s) modificación(es)
Tamaño de la muestra	7a	Cómo se determinó el tar
	7b	Si corresponde, explicar cualquier análisis intermedio y las reglas de interrupción

Científico y ético

Métodos: sección 3 - 12

Métodos		
Aleatorización		

ASIGNACIÓN ALEATORIA



Videla S, Sust M. ICB digital 2003;

ACTORES – ASIGNACIÓN ALEATORIA

LOGÍSTICA OPERACIONAL

OCULTACIÓN

DOBLE CIEGO

ACTORES – ASIGNACIÓN ALEATORIA

LOGÍSTICA OPERACIONAL

OCULTACIÓN

DOBLE CIEGO

CONSORT 2010. Métodos: sección 3 - 12

Métodos		
Aleatorización		
Generación de la secuencia	8a	Método utilizado para generar la secuencia de asignación aleatoria

"For allocation of the participants, **a computer generated list of random numbers was used**"

[Fox et al. Lancet 2008;372:807e16]

"Randomization sequence was created using Stata 9.0 (StataCorp, College Station, TX) statistical software"

[Creinin et al. Obstet Gynecol2008;111:267e77]

CONSORT 2010. Métodos: sección 3 - 12

Métodos		
Aleatorización		
Generación de la secuencia	8a	Método utilizado para generar la secuencia de asignación aleatoria

"Participants were randomly assigned following simple randomization procedures **(computerized random numbers)** to 1 of 2 treatment groups"

[Tate et al. JAMA 2003;289:1833e6.]

"Independent pharmacists dispensed either active or placebo inhalers according to **a computer-generated randomisation list"** [Bolliger et al. BMJ 2000;321:329e33]

CONSORT 2010. Métodos: sección 3 - 12

Métodos		
Aleatorización		
Generación de la secuencia	8a	Método utilizado para generar la secuencia de asignación aleatoria
	8b	Tipo de aleatorización; detalles de cualquier restricción (como bloques y tamaño

"Randomization sequence was created using Stata 9.0 (StataCorp, College Station, TX) statistical software **and was stratified by center with a 1:1 allocation using random block sizes of 2, 4, and 6"** [Creinin et al. Obstet Gynecol 2008;111: 267e77]

"Participants were randomly assigned following simple randomization procedures (computerized random numbers) **to 1 of 2 treatment groups"** [Tate et al. JAMA 2003;289:1833e6]

CONSORT 2010. Métodos: sección 3 - 12

“The doxycycline and placebo were in capsule form and identical in appearance. They were prepacked in bottles and consecutively numbered for each woman according to the randomisation schedule. Each woman was assigned an order number and received the capsules in the corresponding prepacked bottle”

[Sinei et al. Br J Obstet Gynaecol 1990;97:412e9]

“Independent pharmacists dispensed either active or placebo inhalers according to a computer generated randomisation list’’

[Bolliger et al. BMJ2000;321:329e33]

CONSORT 2010. Métodos: sección 3 - 12

Métodos		
Aleatorización		
Implementación	10	Quién generó la secuencia de asignación aleatoria, quién seleccionó a los participantes y quién asignó los participantes a las intervenciones

"Block randomisation was by a computer generated random number list prepared by **an investigator with no clinical involvement in the trial**. We stratified by **admission** for an **oncology related procedure**. After the research nurse had obtained the patient's consent, she telephoned **a contact** who was independent of the recruitment process for allocation consignment"

[Webster et al. BMJ 2008;337: a339.]

CONSORT 2010. Métodos: sección 3 - 12

Métodos		
Aleatorización		
Implementación	10	Quién generó la secuencia de asignación aleatoria, quién seleccionó a los participantes y quién asignó los participantes a las intervenciones
Enmascaramiento	11a	if someone is involved in the sequence generation or allocation concealment steps, ideally they should not be involved in the implementation step.
	11b	

Métodos: sección 3 - 12

“Whereas patients and physicians allocated to the intervention group were aware of the allocated arm, outcome assessors and data analysts were kept blinded to the allocation”

[Smith et al. Mayo Clin Proc 2008;83:747e57]

Enmascaramiento	11a	Si se realizó, a quién se mantuvo cegado después de asignar las intervenciones (por ejemplo, participantes, cuidadores, evaluadores del resultado) y de qué modo
	11b	Si es relevante, descripción de la similitud de las intervenciones

CONSORT 2010. Métodos: sección 3 - 12

Métodos		
Métodos estadísticos	12a	Métodos estadísticos utilizados para comparar los grupos en cuanto a la variable respuesta principal y las secundarias
	12b	Métodos de análisis adicionales, como análisis de subgrupos y análisis ajustados

Protocolo

⇓

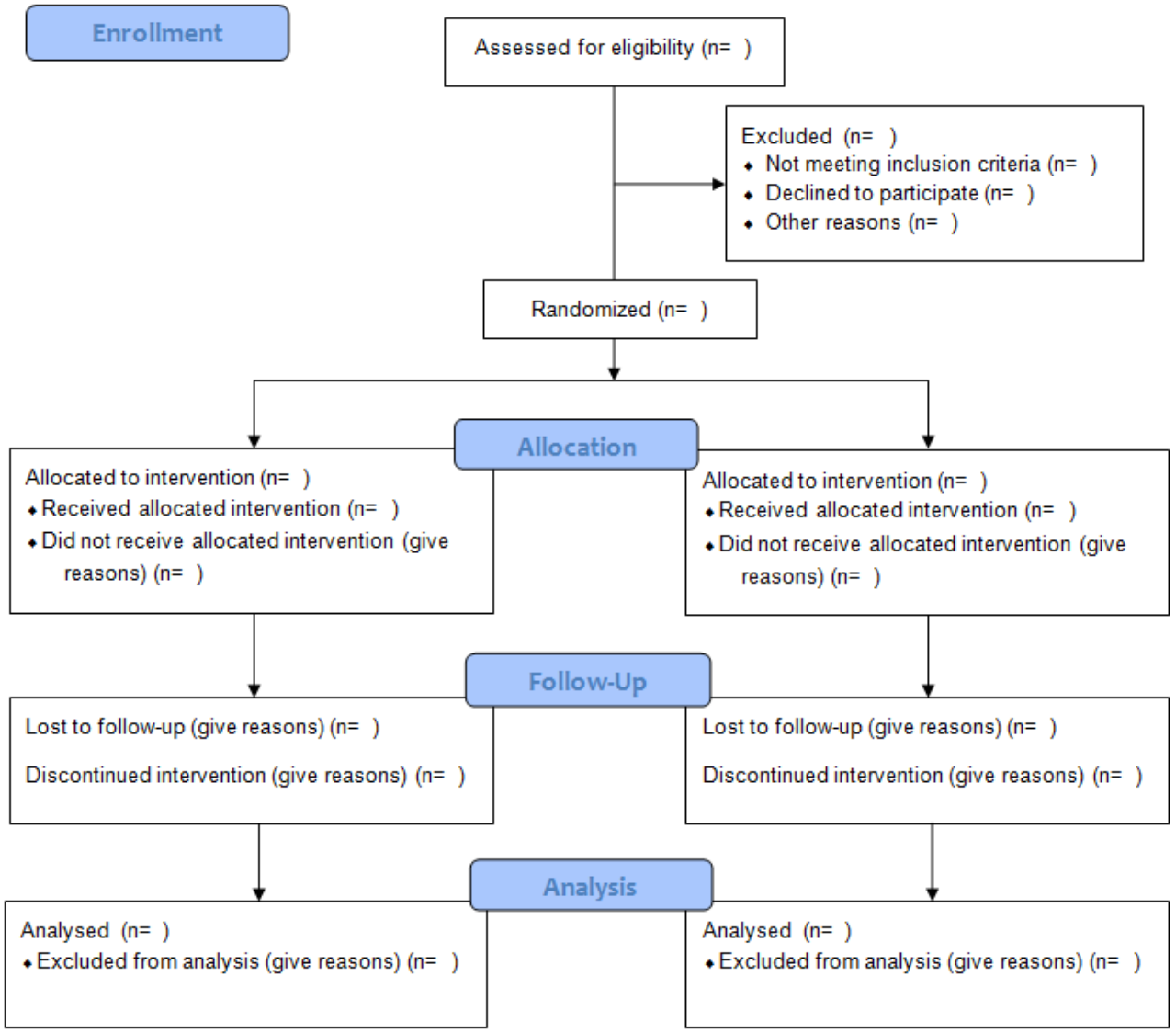
Statistical Analysis Plan

Populations: “Intention-To-Treat” / “Per Protocol”

CONSORT 2010. Resultados: sección 13 - 19

Resultados		
Flujo de participantes (se recomienda encarecidamente un diagrama de flujo)	13a	Para cada grupo, el número de participantes que se asignaron aleatoriamente, que recibieron el tratamiento propuesto y que se incluyeron en el análisis principal
	13b	Para cada grupo, pérdidas y exclusiones después de la aleatorización, junto con los motivos
Reclutamiento	14a	
	14b	

CONSORT 2010 Flow Diagram



CONSORT 2010. Resultados: sección 13 - 19

Resultados		
Flujo de	13a	Para cada grupo, el número de participantes [illegible]

"Between December 2013 and November 2017, 674 patients with MRSAB were evaluated. Of them, 167 patients were randomized and received the study medication… Participants attended clinic visits at the time of randomisation (baseline) and the follow-up visit according with the scheduled"

Reclutamiento	14a	Fechas que definen los períodos de reclutamiento y de seguimiento
	14b	Causa de la finalización o de la interrupción del ensayo

Paradas prematuras !

CONSORT 2010. Resultados: sección 13 - 19

Resultados		
Datos basales	15	Una tabl basales c
Números analizados	16	
Resultados y estimación	17a	
	17b	

Asignación Aleatoria: comparabilidad de los grupos

CONSORT 2010. Resultados: sección 13 - 19

Resultados		
Datos basales	15	Una tabla que muestre las características
Números analizados	16	Para cada grupo, número de participantes (denominador) incluidos en cada análisis y si el análisis se basó en los grupos inicialmente asignados
Resultados y estimación	17a	
	17b	

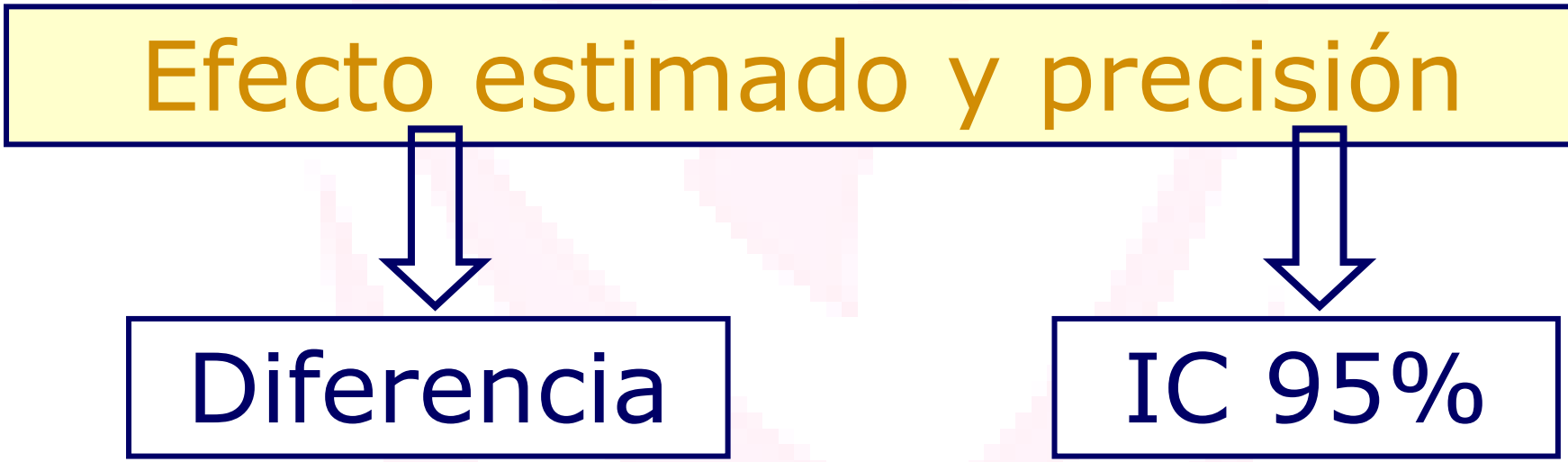
Populations: “Intention-To-Treat” / “Per Protocol”

CONSORT 2010. Resultados: sección 13 - 19

Resultados		
Datos basales	15	Una tabla que muestre las características basales demográficas y clínicas para cada grupo
Números analizados	16	Para cada grupo, número de participantes (denominador) incluidos en cada análisis y si el análisis se basó en los grupos inicialmente asignados
Resultados y estimación	17a	Para cada respuesta o resultado final principal y secundario, los resultados para cada grupo, el tamaño del efecto estimado y su precisión (como inte
	17b	Para las respuestas dicotómicas, se recomienda la presentación de los tamaños del efecto tanto absoluto como relativo

Interpretación clínica más fácil

Resultados: sección 17



Resultados: sección 13 - 19

Table 7 | Example of reporting both absolute and relative effect sizes. (Adapted from table 3 of The OSIRIS Collaborative Group[242])

	Percentage (No)			
Primary outcome	Early administration (n=1344)	Delayed selective administration (n=1346)	Risk ratio (95% CI)	Risk difference (95% CI)
Death or oxygen dependence at "expected date of delivery"	31.9 (429)	38.2 (514)	0.84 (0.75 to 0.93)	−6.3 (−9.9 to −2.7)

CONSORT 2010. Resultados: sección 13 - 19

Resultados		
Análisis secundarios	18	Resultados de cualquier otro análisis realizado, incluido el análisis de subgrupos y los análisis ajustados, diferenciando entre los especificados *a priori* y los exploratorios
Daños (perjuicios)	19	

Cuidado con *Post hoc* análisis

Resultados: sección 13 - 19

Resultados		
Análisis secundarios	18	Resultados de cualquier otro análisis realizado, incluido el análisis de subgrupos y los análisis ajustados, diferenciando entre los especificados *a priori* y los exploratorios
Daños (perjuicios)	19	Todos los daños (perjuicios) o efectos no intencionados en cada grupo (para una orientación especifica, véase CONSORT for harms)

CONSORT 2010. Discusión: sección 20 - 22

Discusión		
Limitaciones	20	Limitaciones del estudio, abordando las fuentes de posibles sesgos, las de imprecisión y, si procede, la multiplicidad de análisis
Generalización	21	Posibilidad de generalización (validez externa, aplicabilidad) de los hallazgos del ensayo
Interpretación	22	Interpretación consistente con los resultados, con balance de beneficios y daños, y considerando otras evidencias relevantes

Validez interna

Validez externa

CONSORT 2010. Otra información: sección 23 - 25

Otra información		
Registro	23	Número de registro y nombre del registro de ensayos
Protocolo	24	Dónde puede accederse al protocolo completo del ensayo, si está disponible
Financiación	25	Fuentes de financiación y otras ayudas (como suministro de medicamentos), papel de los financiadores

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4,5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	no changes happened
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9,10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	no changes happened
Sample size	7a	How sample size was determined	10,11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	non applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	---

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10,11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	12
	14b	Why the trial ended or was stopped	11
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Figure 3, table 2 and 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	13
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	13
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	13,14
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	15,16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	16,17
Other information			
Registration	23	Registration number and name of trial registry	3,6
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2,18

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Una bona investigació
pot no conduir a un bon article
si no es coneix la manera adequada de redactar-ho

Un article mal redactat
pot fer malbé el resultat (l'evidència)

Autoría

Recommendations

Browse

About the Recommendations

Roles & Responsibilities

Defining the Role of Authors and Contributors

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Defining the Role of Authors and Contributors

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Defining the Role of Authors and Contributors

1. Why Authorship Matters

Authorship confers credit and has important academic, social, and financial implications. Authorship also implies responsibility and accountability for published work. The following recommendations are intended to ensure that contributors who have made substantive intellectual contributions to a paper are given credit as authors, but also that contributors credited as authors understand their role in taking responsibility and being accountable for what is published.

Because authorship does not communicate what contributions qualified an individual to be an author, some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research. Editors are strongly encouraged to develop and implement a contributorship policy. Such policies remove much of the ambiguity surrounding contributions, but leave unresolved the question of the quantity and quality of contribution that qualify an individual for authorship. The ICMJE has thus developed criteria for authorship that can be used by all journals, including those that distinguish authors from other contributors.

Defining the Role of Authors and Contributors

2. Who Is an Author?

The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Defining the Role of Authors and Contributors

3. Non-Author Contributors

Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading. Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g. "Clinical Investigators" or "Participating Investigators"), and their contributions should be specified (e.g., "served as scientific advisors," "critically reviewed the study proposal," "collected data," "provided and cared for study patients", "participated in writing or technical editing of the manuscript").

Because acknowledgment may imply endorsement by acknowledged individuals of a study's data and conclusions, editors are advised to require that the corresponding author obtain written permission to be acknowledged from all acknowledged individuals.