Real-time systematic review and meta-analysis of non-randomised comparative treatment studies for COVID-19

First published: 07/05/2020

Last updated: 02/07/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/35988

EU PAS number

EUPAS35147

Study ID

35988

DARWIN EU® study

No

Study countries

☐ Spain

United Kingdom

Study description

A real-time systematic review and meta-analysis of non-randomised studies to compare in-hospital clinical outcomes in patients managed with standard care and various treatments for COVID-19.To compare the results of treatments in non-randomised comparative studies and randomised controlled trials for in-hospital clinical outcomes in COVID-19 patients.

Study status

Ongoing

Research institutions and networks

Institutions

OXON Epidemiology

Spain

United Kingdom

First published: 06/12/2010

Last updated: 15/03/2024

Institution **Laboratory/Research/Testing facility** **Non-Pharmaceutical company** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 08/05/2020

Actual: 08/05/2020

Study start date

Planned: 08/05/2020

Actual: 20/05/2020

Date of final study report

Planned: 10/05/2021

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

GSK, OXON Epidemiology

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To compare in-hospital clinical outcomes in patients managed with standard care and various treatments for COVID-19 in non-randomised studies.To compare the results of treatments in non-randomised comparative studies and randomised controlled trials for in-hospital clinical outcomes in COVID-19

patients.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

HYDROXYCHLOROQUINE

LOPINAVIR

RITONAVIR

AZITHROMYCIN HYDROCHLORIDE

REMDESIVIR

INTERFERON ALFA-2B

INTERFERON BETA-1A

INTERFERON BETA-1B

TOCILIZUMAB

SARILUMAB

SILTUXIMAB

SARS-COV-2 CONVALESCENT PLASMA

Medical condition to be studied

COVID-19

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

0

Study design details

Outcomes

- In hospital death. - In hospital clinical scales and outcomes, mechanical ventilation, renal replacement therapy, admission to ICU, serious complications and serious adverse events.- Duration of hospitalization.- Duration of ICU stay.

Data analysis plan

PAIRWISE META-ANALYSIS OF NON-RANDOMISED COMPARISONS. Fixed or random effects meta-analysis will combine risk, odds and hazard ratios, mean difference and standardised mean differences. The I2 test will assess heterogeneity. Egger´s test and funnel plots for publication and reporting bias.COMPARISON OF META-ANALYSES OF RCTS AND PAIR-WISE NON-RANDOMISED COMPARISONS. Comparison of risk, odds and hazard ratios with 95% confidence interval from meta-analysis of RCTs and pair wise meta-analysis of non-randomised studies, using fixed or random effects. NETWORK META-ANALYSIS OF NON-RANDOMISED COMPARISONS. A network diagram will be made with nodes Transitivity and consistency will be assessed. Heterogeneity will be evaluated with 95% prediction intervals. Interventions will be ranked by surface under the cumulative ranking curve. Heterogeneity and incoherence will be explored. Publication and under-reporting bias will be explored with modified funnel plots.

Documents

Study publications

Nawab Qizilbash, Stuart Pocock, Jesus Lopez Arrieta, Ignacio Mendez, Bélène Pod…

Data management

Data sources

Data sources (types)

Other

Published literature

Data sources (types), other

We will search MEDLINE (PubMed), EMBASE, Cochrane Library, and newer sources since the COVID-19 Pandemic: MedRxiv.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No