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

First published: 07/05/2020
Last updated: 02/04/2024

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 institution and networks

Institutions

OXON Epidemiology

Spain
United Kingdom
First published: 06/12/2010
Last updated
15/03/2024

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

Contact details

Study institution contact
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Study contact

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Primary lead investigator
Nawab Qizilbash MRCP MSc DPhil(Oxon)
Primary lead investigator

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 pati

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