Quality of adverse event reporting in clinicals trials of COVID-19 drugs : a systematic review

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Study Planned

Administrative details

EU PAS number

EUPAS45959

Study ID

46849

DARWIN EU® study

No

Study countries

☐ France

Study status

Planned

Research institutions and networks

Institutions

Toulouse University Hospital

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Institution

Contact details

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Study contact

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Primary lead investigator

François Montastruc

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/01/2022

Study start date

Planned: 18/04/2022

Date of final study report
Planned: 06/06/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

National Research Agency (NRA)

Study protocol

Protocole.pdf(217.25 KB)

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:

Drug utilisation

Main study objective:

the main goal of this systematic review, is to assess the quality of adverse event reporting in clinical trials of COVID-19 drugs

Study Design

Non-interventional study design

Systematic review and meta-analysis

Population studied

Age groups

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

Renal impaired

Estimated number of subjects

100

Study design details

Data analysis plan

we will calculate the proportion of monoclonal, antiviral and immunomodulatory antibodies that are of high, moderate, low or very low quality. For the first secondary objective, we will calculate for each drug, the proportion of studies that use "standardized" methods as the double-blind method according to the quality of their reporting of adverse events. i.e. calculate the proportion of studies using the double-blind method in the category of studies with a high, moderate, low and very low score. Finally, for the second secondary objective, we will make a comparison between the serious adverse events reporting in trial articles published and their associated clinical trial summaries. For that, we will calculate the percentage of consistent and different serious adverse events between the two sources.

Data management

ENCePP Seal

Conflicts of interest of investigators

Declaration of Interests-Annex5-i.pdf(86.47 KB)

Composition of steering group and observers

Composition of Steering Group and ObserversDocument.pdf(46.68 KB)

Signed code of conduct

Déclaration à signer -signed.pdf(116.04 KB)

Signed code of conduct checklist

Annexe 2 à signer .pdf(209.61 KB)

Data sources

Data sources (types)

Published literature

Other

Data sources (types), other

The pubMed database

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