

Description of international collaboration in the area of medicines use and effects in COVID-19 affected pregnancies (CONSIGN-International))

First published: 31/03/2021

Last updated: 23/05/2024

Study

Planned

Administrative details

EU PAS number

EUPAS40317

Study ID

49130

DARWIN EU® study

No

Study countries

☐ Belgium

☐ Canada

☐ Denmark

- ☐ Finland
 - ☐ Germany
 - ☐ Iceland
 - ☐ Italy
 - ☐ Netherlands
 - ☐ Norway
 - ☐ Saudi Arabia
 - ☐ Spain
 - ☐ Sweden
 - ☐ Switzerland
 - ☐ United Kingdom
 - ☐ United States
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Study description

This document describes ongoing initiatives and opportunities for international collaboration in the area of medicines use and their effects on management of COVID-19 in pregnancy. We will call this CONSIGN-International. The current entry in the EUPAS register includes a general description of international collaboration and a protocol and statistical analysis plan of a meta-analysis of the existing data collections.

Study status

Planned

Research institutions and networks

Institutions

University Medical Center Utrecht (UMCU)

☐ Netherlands

First published: 24/11/2021

Last updated: 22/02/2024

Institution

Educational Institution

Hospital/Clinic/Other health care facility

ENCePP partner

Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

☐ Netherlands

First published: 01/03/2010

Last updated: 23/05/2024

Institution

Educational Institution

ENCePP partner

Fundació Institut Català de Farmacologia (FICF)

☐ Spain

First published: 29/03/2010

Last updated: 17/09/2019

Institution

Educational Institution

Hospital/Clinic/Other health care facility

Not-for-profit

ENCePP partner

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

☐ Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution

Educational Institution

ENCePP partner

University Medical Center Utrecht (UMCU)

☐ Netherlands

First published: 24/11/2021

Last updated: 22/02/2024

Institution

Educational Institution

Hospital/Clinic/Other health care facility

ENCePP partner

RTI Health Solutions (RTI-HS)

☐ France

☐ Spain

- ☐ Sweden
- ☐ United Kingdom
- ☐ United Kingdom (Northern Ireland)
- ☐ United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution

Not-for-profit

ENCePP partner

Bordeaux PharmacoEpi, University of Bordeaux

- ☐ France

First published: 07/02/2023

Last updated: 08/02/2023

Institution

Educational Institution

Hospital/Clinic/Other health care facility

Not-for-profit

ENCePP partner

Instituto Aragonés de Ciencias de la Salud (IACS)

- ☐ Spain

First published: 01/02/2024

Last updated: 02/04/2024

Institution

Educational Institution

Swansea University Medical School

☐ United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Educational Institution

Hospital/Clinic/Other health care facility

The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

☐ Spain

First published: 01/02/2024

Last updated: 05/11/2024

Institution

Karolinska Institutet

☐ Sweden

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Educational Institution

University of Manchester

☐ United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Educational Institution

University of Oslo

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University of Copenhagen Denmark, University of Oxford UK, FISABIO Spain, Karolinska Institutet Sweden, University of Oslo Norway, Instituto Aragonés de Ciencias de la Salud (IACS) Spain, Swansea University UK, University of Bern Switzerland, University of Manchester UK, - George Washington University - SFDA - SET-NET (CDC) - Health Canada - CAMCCO - FDA - Sentinel - University of Lausanne (CHUV) International collaborators

Networks

EU Pharmacoepidemiology and Pharmacovigilance (PE&PV) Research Network

☐ Netherlands

First published: 01/02/2024

Last updated: 26/11/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Miriam Sturkenboom

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/07/2020

Actual: 17/07/2020

Study start date

Planned: 01/01/2021

Data analysis start date

Planned: 01/09/2022

Date of interim report, if expected

Planned: 31/03/2023

Date of final study report

Planned: 28/07/2023

Sources of funding

- Other

More details on funding

EMA

Study protocol

[Deliverable 2b by the EU PE&PV research network for the CONSIGN project version1.1_20210312.pdf\(1.28 MB\)](#)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

This is an EMA-tendered study

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

If 'other', further details on the scope of the study

Medicines to treat COVID-19 in pregnant women

Main study objective:

Description of international collaboration in the area of medicines use and effects in COVID-19 affected pregnancies with two key objectives 1) Use of medicines to treat COVID-19 in pregnancy 2) Effects of medicines used to treat COVID-19 in pregnancy on maternal, pregnancy and perinatal outcomes.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

1000000

Study design details

Outcomes

Maternal, pregnancy and neonatal outcomes

Data analysis plan

CONSIGN International will focus on two key objectives: 1) & 2) as stated. The aim of our international meta-analysis is to describe the use of medicines to treat COVID-19 disease by trimester of pregnancy and the effects of medicines used to treat COVID-19 on maternal, pregnancy and neonatal outcomes and to pool as much data available around the world with similar protocols and settings. To pool the available data, we will conduct two meta-analyses

including prospective and retrospective data collection with reliable data on the different classes of these medicines and associated perinatal outcomes in a real-world clinical setting: the first combining population-based health care data sources (meta-analysis 1) and the second combining case-based registries compiled by health care professionals (meta-analysis 2). For further details regarding the data analysis we refer to our CONSIGN international meta-analysis protocol and statistical analysis plan.

Documents

Study publications

[Sturkenboom, MCJM, Nordeng, H, Klungel, O, Margulis, A, Poblador, D, Siiskonen,...](#)

[de Bruin, O, Maisonneuve, E, Sturkenboom, MCJM. Description and characterizatio...](#)

[É. Maisonneuve, O. de Bruin, E. Hurley, H. Nordeng, S.J. Siiskonen, F. Ahmadiza...](#)

Data management

Data sources

Data sources (types)

[Other](#)

Data sources (types), other

The sources of data are available at the study sites in collaboration with CONSIGN group. There are 2 different types of data sources: 1) secondary use

of health care data, which will mostly capture outpatient treatment, and 2) case based data collection from health clinics.

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