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

PURI
https://redirect.ema.europa.eu/resource/49130

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

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 institution 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
19/02/2024

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 01/02/2024

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
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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