CONSIGN study: COVID-19 infection and medicines in pregnancy - a multinational registry based study

First published: 10/02/2021
Last updated: 22/04/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/48598

EU PAS number
EUPAS39438

Study ID
48598

DARWIN EU® study
No

Study countries
Denmark
France
Germany
Italy
Norway
Spain
Sweden
United Kingdom

Study description
A retrospective multi-database dynamic cohort study, conducted during the years 2018 to 2020, including a period of SARS-CoV-2 circulation in Europe. The study population includes women of reproductive age (12-55 years), pregnant women and their children. The study will include data from 9 electronic health care registries in 8 European countries. Descriptive analysis will focus on 3-monthly prevalence rates of medication use, incidence rates of COVID-19 outcomes and prevalence of pregnancy outcomes. The primary objectives are: 1) To estimate the prevalence of medicines used, by trimester of pregnancy, and compare this among pregnant women with COVID-19, pregnant women without COVID-19, and non-pregnant women with COVID-19. 2)To describe severity and clinical outcomes of COVID-19 disease in pregnant women with COVID-19, according to treatments received during pregnancy, and compare these data with those of nonpregnant women of reproductive age with COVID-19. 3) To assess and compare the rates of adverse maternal and neonatal outcomes in pregnant women with and without COVID-19, using different medicines.

Study status
Ongoing

Research institution and networks

Institutions

University of Oslo
First published: 01/02/2024
Last updated 01/02/2024
Institution

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

Pharmacoepidemiology and Drug Safety Research Group (PharmaSafe), University of Oslo

Norway
First published: 19/10/2016
Last updated 08/11/2016

Institution | Educational Institution | ENCePP partner

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany
First published: 29/03/2010
Last updated 26/02/2024

Institution | Not-for-profit | 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

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

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden
First published: 24/03/2010
Last updated
23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | 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

Aarhus University Hospital

First published: 01/02/2024
Last updated
01/02/2024

Institution

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

University of Oslo

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01/02/2024

Institution

University of Oslo Norway, Aarhus University Hospital Denmark, University of Copenhagen Denmark, FISABIO Spain, IACS Spain, Swansea University UK

Networks

EU Pharmacoepidemiology and Pharmacovigilance (PE&PV) Research Network

Netherlands
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23/05/2024

Network

Contact details

Study institution contact
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Primary lead investigator
Hedvig Nordeng
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
Actual:
01/01/2021

Date of interim report, if expected
Planned:
14/10/2021

Date of final study report
Planned:
28/07/2023

Sources of funding

- Other

More details on funding

EMA

Study protocol

ProtocolCONSIGNWP1v1.0_EUPASS.pdf(2.11 MB)

EUPAS39438 CONSIGN WP1 protocol including amendment 1.pdf(2.31 MB)

Regulatory

Was the study required by a regulatory body?
Yes

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:
Assessment of risk minimisation measure implementation or effectiveness
Drug utilisation

Main study objective:
To estimate prevalence of medicines use in pregnant COVID-19 patients and to describe severity of clinical outcomes as well as pregnancy and neonatal outcomes

Study Design

Non-interventional study design
Case-control

Cohort

Population studied

Age groups
Adolescents (12 to < 18 years)
Adults (18 to < 46 years)
Adults (46 to < 65 years)

Special population of interest
Hepatic impaired
Immunocompromised
Pregnant women
Renal impaired

Estimated number of subjects
1000000

Study design details

Outcomes
Use of medication Severity of COVID-19 Pregnancy and neonatal outcomes

Data analysis plan
Descriptive analysis, matched analysis of cohorts and sensitivity analysis will be conducted.

Documents

Study publications
Hurley, Eimir, Sturkenboom, Miriam, Poblador-Plou, Beatriz, Sanfelix-Gimeno, Ga…
CONSIGN community on Zenodo (includes all publications currently available with…

Data management

Data sources

Data source(s)
Danish registries (access/analysis)
German Pharmacoepidemiological Research Database
ARS Toscana

Data source(s), other
Danish Registries (access/analysis), NorPD, GePaRD, ARS

Data sources (types)
Administrative data (e.g. claims)
Disease registry
Drug dispensing/prescription data
Electronic healthcare records (EHR)
Other

Data sources (types), other
Prospective patient-based data collection, Exposure registry

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