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 institutions 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: 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

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: 05/11/2024

Institution

University of Oslo

First published: 01/02/2024

Last updated: 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

First published: 01/02/2024

Last updated: 26/11/2024

Network

Contact details

Study institution contact

Hedvig Nordeng

Study contact

h.m.e.nordeng@farmasi.uio.no

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 healthcare records (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