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

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Institution | Outdated | Educational Institution | ENCePP partner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Institution | Outdated | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner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

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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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Network

Contact details

Study institution contact

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Study 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

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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

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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