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

First published: 10/02/2021

Last updated: 22/04/2024





Administrative details

EU PAS number	
EUPAS39438	
Study ID 48598	
DARWIN EU® study	
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 3monthly 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

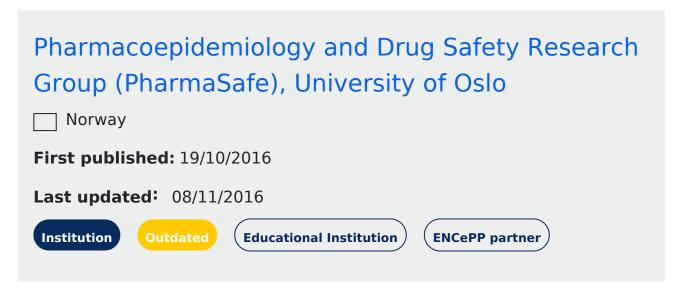
University of Oslo

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Institution





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de Farmacologia (FICF) ☐ Spain **First published: 29/03/2010 Last updated:** 17/09/2019 **Educational Institution** Outdated Institution Hospital/Clinic/Other health care facility Not-for-profit **ENCePP** partner University Medical Center Utrecht (UMCU) Netherlands **First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	
Not-ior-profit	

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

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University of Oslo

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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

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

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