COVID-19 infections and medicines in pregnancy- the INOSS collaboration (INOSS CONSIGN)

First published: 29/04/2021

Last updated: 02/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS40489

Study ID

40490

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Denmark
- [ ] Finland
- [ ] France

- [ ] Iceland
- [ ] Italy
- [ ] Norway
- [ ] Slovakia
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

Few studies about the consequences of COVID-19 infection in pregnancy are population based. Countries participating in the International Network of Obstetric Survey Systems (INOSS) conduct national or regional, population-based studies of severe pregnancy complications. The network was established in 2010 and has established protocols and core data items, enabling both prospective and retrospective individual patient data meta-analyses. All the INOSS national teams have established studies of COVID-19 in pregnancy. Previous projects have demonstrated that these systems can be used to rapidly collect information to inform policy and guidance in previous pandemics and in other emerging infections. These experiences enabled the network to commence unified, comparable national studies with common protocols and definitions in response to the SARS-CoV-2 pandemic. Crucially, these studies cover the entire national or regional populations, thus we can be confident that all women with SARS-CoV-2 complications in pregnancy are identified and estimated complication rates are accurate and not subject to case ascertainment or reporting bias. The study population in the current study are pregnant women admitted to hospital with a positive PCR test maximum 7 days prior to admission or within 2 days postpartum. The study will determine the incidence of hospitalization, the influence of medical treatment for covid-19 and maternal and neonatal outcomes in women treated or not treated with covid-19 medication such as antiviral therapies. Analyses will be performed using a 2

step individual patient data meta analysis, with primary analyses on a national level and subsequent meta analyses on the merged dataset.

Study status

Ongoing

Research institutions and networks

Institutions

University Medical Center Utrecht (UMCU)

Netherlands

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Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **ENCePP partner**

Networks

International Obstetric Survey Systems

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kitty Bloemenkamp

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/07/2020

Actual: 17/07/2020

Study start date

Planned: 01/02/2020

Actual: 01/03/2020

Date of interim report, if expected

Planned: 29/01/2021

Actual: 29/01/2021

Date of final study report

Planned: 15/07/2021

Sources of funding

- Other

More details on funding

K. W. M. Bloemenkamp

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:

Disease epidemiology

Drug utilisation

Main study objective:

Primary objectives: To determine: I. The incidence frequency of hospitalisation with COVID-19 disease in pregnancy across multiple EU and non-EU nations. II. The COVID-related outcomes of hospitalisation with COVID-19 disease in

pregnancy for mother and infant. III. Medication use in COVID-19 positive pregnant women admitted to hospital.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Medical condition to be studied

Acute respiratory distress syndrome

Additional medical condition(s)

Maternal and neonatal respiratory support

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

2500

Study design details

Outcomes

Maternal and neonatal Intensive care unit admission, need for ventilatory support, maternal or perinatal death including stillbirth, delivery by cesarean section, preterm delivery (<37 gestational weeks), infant with severe growth restriction (birth weight <10 percentile according to Intergrowth standards)

Data analysis plan

To estimate the associations between medicines use during a hospitalization for COVID-19 in pregnant women and pregnancy, maternal and neonatal outcomes, nested case control analyses will be conducted. Cases will be the women with completed pregnancies with adverse outcomes, controls are women with completed pregnancies without the adverse outcome. Characteristics of cases (separately for each outcome) and controls will be described and tested utilizing logistic regression analysis. The effect of medicines use will be estimated utilizing logistic regression, adjustments will be made for all factors that change the effect estimate with more than 10%. For metaanalysis we use a two-stage hybrid approach for pooling case-control data from study sites. Random effects meta-analyses will be performed overall and stratified by subgroups. Descriptive analyses of characteristics and distribution of outcomes and by analysing crude and adjusted odds ratios.

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 sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection

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