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

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# 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, populationbased 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**



## **Networks**

International Obstetric Survey Systems

## Contact details

**Study institution contact** 

## Kitty Bloemenkamp K.W.M.Bloemenkamp@umcutrecht.nl

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

## 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