COVID-19 in Pregnancy in Scotland COVID-19: vaccine safety analyses in pregnant women (COPS)

First published: 20/01/2022

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Study Ongoing

Administrative details

EU PAS number

EUPAS45026

Study ID

45301

DARWIN EU® study

No

Study countries

United Kingdom

Study description

The main aim of this matched cohort study is to assess the safety of receiving COVID-19 vaccines during pregnancy in Scotland. This will be done using routinely collected electronic health records which provide data to identify pregnancies and their outcomes, vaccination status, any confirmed PCR test for SARS-COV-2 infection, and other covariates of interest (e.g. age, ethnicity and deprivation score). These linked data will be used to monitor whether there is evidence that risk of a series of pre-specified pregnancy, maternal and neonatal outcomes is different among women who received a COVID-19 vaccine in pregnancy compared to women who did not receive a COVID-19 vaccine in pregnancy. In our primary analysis, the vaccinated group will comprise of women who received any COVID-19 vaccine in the six weeks preceding conception or at any point between conception and the end of pregnancy between 08 December 2020 to the date of data extraction, and unvaccinated individuals will be identified from the pre-pandemic period (2015 to the start of the pandemic). Three unvaccinated women will be matched to each vaccinated women by maternal age, gestational age and season of conception. Supplementary analyses will be conducted selecting the unvaccinated comparison group from the pandemic period.

Study status

Ongoing

Research institutions and networks

Institutions

Public Health Scotland

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Institution

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Contact details

Study institution contact

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Primary lead investigator

Rachael Wood

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2020

Actual: 01/07/2020

Study start date

Planned: 01/01/2015

Actual: 01/01/2015

Data analysis start date
Planned: 17/01/2022

Date of interim report, if expected
Planned: 01/03/2022

Date of final study report
Planned: 30/09/2022

Sources of funding

- Non-for-profit organisation (e.g. charity)
- Other

More details on funding

Tommy's Charity, Wellcome Trust, Scottish Government DG Health and Social Care, Medical Research Council, UK Research and Innovation Industrial Strategy Challenge Fund

Study protocol

Protocol_VS in pregnancy.pdf (1.27 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Main study objective:

The main aim of this work is to assess the safety of receiving COVID-19 vaccines during pregnancy.

Study Design

Non-interventional study design

Cohort

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

20000

Study design details

Outcomes

The primary outcomes are: - Hypertensive disorders of pregnancy - Venous thromboembolism - Pregnancy-related bleeding - Maternal ICU admission or death - Miscarriage - Ectopic pregnancy - Stillbirth - Any congenital anomaly - Microcephaly - Preterm birth - Spontaneous preterm birth - Small for gestational age - Low Apgar score - Neonatal death - Extended perinatal mortality, The secondary outcomes are: - First trimester miscarriage - Second trimester miscarriage - Any non-genetic congenital anomaly - Severe microcephaly - Very preterm birth - Spontaneous very preterm birth - Very small for gestational age - Very low Apgar score

Data analysis plan

Descriptive analyses will initially be conducted first exploring the key socio-demographic and clinical characteristics of the vaccinated and unvaccinated cohorts, and then calculating the number and risk of each outcome of interest in the vaccinated and unvaccinated groups. Maternal, pregnancy and neonatal outcomes in the vaccinated and unvaccinated pregnant cohorts will be compared using appropriate regression models, including accounting for

competing risks where these are relevant for a particular outcome. We will adjust for potential confounders in these models. We will consider adjusting our modelling approach for rarer outcomes. Full details of the statistical analysis plan can be found here: https://github.com/Public-Health-Scotland/COPS-public/tree/main/Safety%20protocol

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)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Other

Data sources (types), other

These are described in detail in the protocol and the COPS cohort profile (https://doi.org/10.1093/ije/dyab243). There are many data sources included, examples of which are: antenatal booking records, GP records, Scottish Morbidity Record (SMR) 01, SMR 02, Abortion Act Scotland records, National Records of Scotland (NRS) statutory stillbirth registrations and NRS statutory

livebirth registrations.

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