Improving detection of associations between congenital anomalies and medicines taken in the first trimester of pregnancy, using data derived hierarchies.

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Study Planned

Administrative details

EU PAS number

EUPAS49055

Study ID

49056

DARWIN EU® study

No

Study countries

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

- [ ] Ireland
- [ ] Italy
- [ ] Malta
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Switzerland
- [ ] United Kingdom

Study description

Identification of signals of potential harm is an important aspect of drug safety monitoring after regulatory approval. Current signal detection methods focus on the increased occurrence of single defects, but many teratogenic medications result in multiple defects. Different medications may also have similar patterns of associations with specific defects. Statistical methods to simultaneously analyse data on several birth defects and several medications within the EUROmediCAT database have been developed. These methods will be tested on EUROmediCAT data and results will be evaluated and interpreted by an advisory committee consisting of clinical specialists, pharmacologists and geneticist.

Study status

Planned

Research institutions and networks

Institutions

St George's University of London

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Institution

Networks

EUROmediCAT

Contact details

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Primary lead investigator

Joan Morris

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/10/2021

Actual: 01/10/2021

Study start date
Planned: 01/10/2022

Date of final study report
Planned: 01/09/2024

Sources of funding

- Other

More details on funding

Medical Research Council (MRC)

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:

Other

If ‘other’, further details on the scope of the study

Methodological

Main study objective:

Does the identification of groups of anomalies with similar patterns of association across several medications, and identification of groups of medications with similar patterns of association across several anomalies, improve signal detection of teratogens within the EUROmediCAT database?

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-only

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Special population of interest

Pregnant women

Estimated number of subjects

33000

Study design details

Data analysis plan

Suitable statistical methods to simultaneously analyse data on multiple birth defects and multiple medications within the EUROmediCAT database have been developed by searching the literature for application of similar methods in other fields of research and adapting such methods. An advisory committee containing specialists, pharmacologists and geneticists has been created to assist in model selection and interpretation of results. Chosen methods will be applied initially to a drug and anomaly blinded EUROmediCAT database, with additional information from the EUROCAT database incorporated into models where appropriate. Final model selection will be supported by the advisory team based on the simulation performance and blinded results. The chosen model(s) will then be applied to data from the EUROmediCAT and EUROCAT databases. The advisory committee will assist and support the interpretation of results, including assimilation of new signals with known teratogens.

Data management

Data sources

Data source(s)

EUROmediCAT central database

Data sources (types)

Disease 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