EUROmediCAT: Safety of Medication Use in Pregnancy in Relation to Risk of Congenital Malformations

First published: 29/01/2012

Last updated: 29/01/2012

Study Ongoing

Administrative details

EU PAS number

EUPAS2221

Study ID

2222

DARWIN EU® study

No

Study countries

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

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

Study description

A variety of complementary approaches are needed to evaluate safety of medicine use in pregnancy. To evaluate safety in relation to teratogenicity (capacity to cause malformations), population-based congenital anomalies registers, which are already networked across Europe (EUROCAT) with a common database, can provide a cost-effective mechanism which is as yet underexploited. The enormous population coverage of registers when combined gives sufficient statistical power for the identification of associations between specific drugs and specific malformations. This project will develop and test an efficient pharmaco-vigilance system for safety of drugs during pregnancy in relation to teratogenicity by (i) enhancing the information regarding drug exposure in the EUROCAT database, covering a total population of 6 million births 1995-2010, through linkage to electronic databases containing prescription information, and by linkage to chronic disease cohorts (ii) analysing the enhanced EUROCAT database in relation to four drug groups of public health concern – new antiepileptics, insulin analogs, SSRI antidepressants, and antiasthmatics – exposure to all of which is increasing in the pregnancy population (iii) interrogating health care databases to monitor the effectiveness of drug safety recommendations and pregnancy prevention programmes through drug utilisation studies, and to provide an exposure profile for pregnant women (iv) conducting a scoping study of the implications for drug safety of growing internet use by pregnant women, in terms of access to safety

information about teratogenicity, and access to drugs with teratogenic potential.

Study status

Ongoing

Research institutions and networks

Institutions

Ulster University

United Kingdom (Northern Ireland)

First published: 01/02/2024

Last updated: 20/03/2024

Institution **Educational Institution**

Centre for Maternal, Fetal and Infant Research (MFIR), Ulster University

United Kingdom (Northern Ireland)

First published: 31/01/2023

Last updated: 20/03/2024

Institution **Educational Institution** **ENCePP partner**

Pharmacy & Pharmacology, University of Bath

United Kingdom

First published: 30/04/2010

Last updated: 08/04/2019

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

University of Groningen

Netherlands

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

University of Groningen (RUG) Netherlands, The Academisch Ziekenhuis Groningen/University Medical Center Groningen Netherlands, Paediatric Department, Hospital Lillebaelt - Kolding Denmark, The Poznan University of Medical Sciences (PUMS) Poland, Institute of Clinical Physiology - National Research Council (IFC-CNR) Italy, Swansea

University /Abertawe Bromorgannwg University Health Board UK, Queen Mary University of London UK, Provinciaal Instituut voor Hygiene, Antwerp Belgium, Department of Public Health, Cork Ireland, Department of Health Information Malta

Networks

European Surveillance of Congenital Anomalies (EUROCAT)

- [ ] Austria
- [ ] Belgium
- [ ] Croatia
- [ ] Czechia
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Hungary
- [ ] Ireland
- [ ] Italy
- [ ] Malta
- [ ] Netherlands
- [ ] Norway

- [ ] Poland
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

First published: 30/11/2016

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Network ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Helen Dolk

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 21/02/2011

Study start date
Actual: 01/03/2011

Data analysis start date
Actual: 01/09/2011

Date of interim report, if expected
Planned: 31/10/2012

Date of final study report
Planned: 29/05/2015

Sources of funding

- EU institutional research programme
- Other

More details on funding

FP7, Universities

Regulatory

Was the study required by a regulatory body?

No

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:

The central aim is to build a European system for reproductive safety evaluation, which enables us to identify systematically and comprehensively the possible adverse effects in pregnancy of a drug in humans at the earliest stage post marketing, and enables us to monitor and evaluate safety measures undertaken in Europe.

Study Design

Non-interventional study design

Cohort

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06A) ANTIDEPRESSANTS

ANTIDEPRESSANTS

(N03) ANTIEPILEPTICS

ANTIEPILEPTICS

(A10) DRUGS USED IN DIABETES

DRUGS USED IN DIABETES

(R03) DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

(D10AD04) isotretinoin

isotretinoin

Medical condition to be studied

Congenital cardiovascular anomaly

Neural tube defect

Cleft lip and palate

Cleft palate

Hypospadias

Hydrocephalus

Microcephaly

Gastroschisis

Renal aplasia

Trisomy 21

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Special population of interest

Pregnant women

Estimated number of subjects

120000

Study design details

Outcomes

An efficient system for methodical safety evaluation of drugs during pregnancy, based on an existing network of congenital anomalies registers in Europe and healthcare databases.A quantified risk of congenital anomaly related to new antiepileptics, insulin analogues, anti-asthmatics and SSRIs. A framework to evaluate the efficacy of pregnancy-related drug safety measures.

Data analysis plan

Workpackages 4,5: For three classes of medication (antiepileptics, antidepressants, antiashtmatics) we will analyse the specificity of association between specific medications and specific malformation types, using odds ratios, from a case-malformed control design.Workpackage 4: For insulin analogs, we will use a cohort design and relative risk of malformation.For Workpackage 6, a drug utilisation study, we will use prevalence of medication use during pregnancy.For Workpackage 7 concerning internet use by pregnant women, qualitative and survey methods.

Documents

Study, other information

All 17 Research Centres involved in Study (Q2).pdf(186.47 KB)

Complete List of Conditions Being Studies (Q7).pdf(378.91 KB)

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)

Clinical Practice Research Datalink

IADB.nl

Data source(s), other

Emilia Romagna GPs drug prescription

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, Case-control surveillance database

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