Analysis of pregnancy pharmacovigilance data in spontaneous reports, and literature, (Individual Case Safety Reports originating from published case series, non-interventional studies and patient support programmes); demonstration study 2.5.1 of the ConcePTION project

First published: 06/01/2021

Last updated: 23/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS38841

Study ID

39263

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Netherlands
- [ ] South Africa
- [ ] Switzerland
- [ ] United Kingdom

Study description

Since limited data from studies performed pre-marketing are usually available before licensure of a medicinal product, we have to rely on post-marketing data from both primary as well as secondary data sources. The IMI funded ConcePTION project aims to enhance the way drug use during pregnancy is studied. This is in part achieved by improving the collection, analysis and interpretation of pharmacovigilance (PV) data, to allow for a more systematic analysis and exchange of data. Work Package 2 (WP2) focusses on sources of primary data collection, such as spontaneous reports, data collected by Teratogen Information Services (TIS), literature, pregnancy registries, and enhanced PV studies. Tools developed for the analysis of spontaneous reports, however, were not specifically aimed at the analysis of safety information related to pregnancy. As a first step, this demonstration study will aim to gain insight into the nature of information on drug exposure during pregnancy from spontaneous reports and literature reports as filed in the ICSR databases of national PV centres and Marketing Authorisation Holders. The category literature reports therefore encompass Individual Case Safety Reports originating from published case series, non-interventional studies and Patient Support Programmes. In order to achieve this general aim, 5 sub-studies have been designed. The first sub-study aims to describe the nature and content of spontaneous reports and literature data sources. The second sub-study aims to create and validate a dedicated assessment tool for measuring the clinical quality of pregnancy data specifically, and the third sub-study aims to use this

newly developed tool in order to describe the quality of reports in spontaneous reports and literature. Sub-study 4 will assess predictors of currently used teratogen signal detection techniques in ICSR databases and sub-study 5 aims to explore cluster analysis as a possible new teratogen signal detection technique.

Study status

Planned

Research institutions and networks

Institutions

Netherlands Pharmacovigilance Centre Lareb

Netherlands

First published: 05/02/2010

Last updated: 19/07/2016

Institution **Not-for-profit** **ENCePP partner**

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Novartis Pharmaceuticals

First published: 01/02/2024

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Institution

Novo Nordisk

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Swiss Teratogen Information Service

First published: 01/02/2024

Last updated: 01/02/2024

Institution

KRISP University of KwaZulu-Natal Durban, South Africa, Novartis Pharma AG Basel, switzerland, Novo Nordisk Bagsvaerd, Denmark, Swiss Teratogen Information Service Lausanne, Switzerland, UK Teratology Information Service

Newcastel United Kingdom

Networks

ConcepTION

First published: 01/02/2024

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Network

Contact details

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Primary lead investigator

Eugene van Puijenbroek

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/09/2018

Study start date
Planned: 01/04/2021

Date of final study report
Planned: 01/04/2024

Sources of funding

- EU institutional research programme

More details on funding

Innovative Medicines Initiatiive

Study protocol

Protocol_ConcePTION_Demo2_5_1_V1.0 .pdf(1.19 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:

To gain insight into the nature of information on drug exposure during pregnancy from spontaneous reports and literature reports

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive study in primairy data collections

Study drug and medical condition

Medical condition to be studied

Pregnancy

Stillbirth

Abortion spontaneous

Ectopic pregnancy

Congenital anomaly

Foetal growth restriction

Exposure during pregnancy

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

1000

Study design details

Data analysis plan

data analysis plans are described under the various substudies s1-s5

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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

ENCePP DoIForm_v1.6_EvP.pdf(890.4 KB)

Composition of steering group and observers

EUPAS38841_steering group.pdf(317.33 KB)

Signed code of conduct

ENCePPCoCAnnex3_DeclarationofcompliancewiththeENCePPCodeofConduct.pdf (628.94 KB)

Signed code of conduct checklist

EUPAS38841-38876.pdf(896.47 KB)

Signed checklist for study protocols

ENCePP Checklist for Study Protocols_YW.pdf(495.81 KB)

Data sources

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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