Building a pregnancy pharmacovigilance model for the future: Can pregnancy data collected by ConcePTION partners be analysed using common standards developed by the ConcePTION project?

First published: 04/10/2021

Last updated: 23/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS43370

Study ID

43371

DARWIN EU® study

No

Study countries

Denmark

France

Germany

Israel

Netherlands

South Africa

Switzerland

United Kingdom

Study description

The objective of this pilot study is to determine whether pregnancy data collected by ConcePTION partners can be analysed using common data standards, common clinical and technical definitions, and common reporting algorithms developed by the ConcePTION project. This study will test the degree to which data from various data access providers (DAPs) can conform to the definitions of the Core Data Elements (CDEs) established in ConcePTION. In particular, it will be evaluated whether conversion of the data structures of individual DAPs is possible in terms of clinical perspectives and technical processing perspectives. The feasibility of populating predefined table shells with existing pregnancy data from various data access providers will be tested. Prospective and retrospective cases from exposures in pregnancy and the peri-LMP period to drugs used for the indication of multiple sclerosis from the primary data collections participating in the ConcePTION project will be used in this pilot study. Pregnancy exposure reports in scope for this study will be obtained from three types of data collection methods: pregnancy registries (Gilenya (Novartis), Aubagio (Sanofi), the Dutch Pregnancy Drug Register), EFPIA enhanced pharmacovigilance (PRIM) programmes (Gilenya, Siponimod and ofatumumab (Novartis), worldwide pregnancy surveillance program of oral cladribine (MAPLE-MS) (Merck Healthcare KGaA)), and data from selected European Network of Teratology Information Services (ENTIS) databases. The ability of each DAP to create an analysis dataset of elements conforming to the definitions of the CDEs established in ConcePTION task 2.3 of Work Package 2

will be described and discussed together with the processes used by them. Using this dataset each DAP will be asked to populate pre-defined summary tables according to the guidance in the Statistical Analysis Plan.

Study status

Planned

Research institutions and networks

Institutions

Swiss Teratogen Information Service

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Novo Nordisk

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Sanofi

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Netherlands Pharmacovigilance Centre Lareb

Netherlands

First published: 05/02/2010

Last updated: 19/07/2016

Institution | Outdated | Not-for-profit | ENCePP partner

Shamir Medical Center

Israel

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Hospital/Clinic/Other health care facility

Merck Sharp & Dohme LLC

United States

First published: 01/02/2024

Last updated: 08/07/2025

Institution | Pharmaceutical company

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

The Israeli Teratology Information Service, Israel Ministry of Health Jerusalem, Israel, Clinical Pharmacology and Toxicology Unit, TIS Zerifin, Shamir Medical Center (Assaf Harofeh), Zerifin, Affiliated to Sackler School of Medicine, Tel-Aviv University Tel Aviv, Israel, KRISP, University of KwaZulu-Natal Durban, South Africa, Merck Healthcare KGaA Darmstadt, Germany, Novartis Pharma AG Basel, Switzerland, Novo Nordisk Novo Alle DK-2880 Bagsvaerd, Denmark, Sanofi Paris, France, UK Teratology Information Service Newcastel United Kingdom

Networks

ConcepTION

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

Ursula Winterfeld ursula.winterfeld@chuv.ch

Study contact

ursula.winterfeld@chuv.ch

Primary lead investigator

Ursula Winterfeld

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/09/2018

Study start date

Planned: 30/09/2021

Date of final study report

Planned: 30/09/2024

Sources of funding

- EU institutional research programme

More details on funding

Innovative Medicines Initiative

Study protocol

Protocol_ConcePTION_Demo_ 2_5_2_V_01.pdf (741.99 KB)

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:

Within the broader aim of building a pregnancy pharmacovigilance model for the future the objective of this study is to determine whether pregnancy data collected by ConcePTION partners can be analysed using common data standards, common clinical and technical definitions, and common reporting algorithms developed by the ConcePTION project.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This study will use data from different ENTIS databases, from prospective pregnancy registries, and from enhanced pharmacovigilance programmes. A descriptive comparison will be made of the various aspects of the different data sources.

Study drug and medical condition

Medical condition to be studied

Multiple sclerosis

Pregnancy

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

1.900

Study design details

Data analysis plan

The ability of each data access provider (DAP) to create an analysis dataset of elements conforming to the definitions of the Core Data Elements (CDEs) established in ConcePTION task 2.3 of Work Package 2 will be described and discussed together with the processes used by them. Using this dataset each DAP will be asked to populate pre-defined summary tables according to the guidance in the Statistical Analysis Plan. Summary tables include information on pregnancy cases reported, pending, lost to follow up, and those with known maternal characteristics and risk factors, and known pregnancy outcomes (pregnancy and fetal outcome including congenital malformation) by timing of exposure. The populated tables will be discussed regarding informal comparisons and comparability between the analyses provided by each DAP.

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), other

Gilenya pregnancy registry (Novartis) Switzerland, Siponimod pregnancy registry (Novartis) Switzerland, Teriflunomide pregnancy registries France, The Dutch Pregnancy Drug Register Netherlands, Gilenya PRIM enhanced pharmacovigilance programme Switzerland

---

Data sources (types)

Other

Data sources (types), other

Spontaneous reporting system, Prospective patient-based data collection, Siponimod and ofatumumab PRIM enhanced pharmacovigilance programme (Novartis). Worldwide pregnancy enhanced pharmacovigilance programme of oral cladribine (Merck). Four Teratology Information Services (TIS) from the UK, Switzerland, and Israel will provide data for this study.

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