Long-term investigation following exposure to individual medicines in utero: The LIFETIME system

First published: 04/10/2021

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS43300

Study ID

47521

DARWIN EU® study

No

Study countries

- [ ] Ireland
- [ ] Netherlands
- [ ] United Kingdom

Study description

This project is one of design and feasibility testing. Initially this project will focus on the development of the LIFETIME System: a set of questionnaires which will be the primary source of standardised data collection and the development of infrastructure to collect the data. Following this, three observational studies will be completed which will investigate validity and feasibility of the proposed system through the collection of primary data.

Study status

Ongoing

Research institutions and networks

Institutions

University of Manchester

United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Netherlands Pharmacovigilance Centre Lareb

Netherlands

First published: 05/02/2010

Last updated: 19/07/2016

Institution | Not-for-profit | ENCePP partner

University of Kwa-Zulu Natal South Africa, UK

Teratology Information Service UK, UK & Ireland

Epilepsy Pregnancy Register UK & Ireland,

Medicines and Health Regulatory Authority UK

Networks

ConcepTION

First published: 01/02/2024

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Rebecca Bromley

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/04/2019

Actual: 01/04/2019

Study start date
Planned: 11/02/2022

Actual: 18/02/2022

Data analysis start date
Planned: 01/06/2022

Actual: 01/09/2022

Date of interim report, if expected
Planned: 30/09/2022

Date of final study report
Planned: 30/09/2023

Sources of funding

- EU institutional research programme

More details on funding

Innovative Medicine Initiative (IMI)

Study protocol

EUPAS43300-43376.pdf(774.81 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:

The investigation into methods of routine surveillance for longer-term child health and neurodevelopmental outcomes in children exposed to medications in utero.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N03AG01) valproic acid

valproic acid

(N03AF01) carbamazepine

carbamazepine

(N03AX09) lamotrigine

lamotrigine

(N03AX14) levetiracetam

levetiracetam

(N03AX15) zonisamide

zonisamide

(N03AX18) lacosamide

lacosamide

(N03AX11) topiramate

topiramate

Medical condition to be studied

Epilepsy

Foetal anticonvulsant syndrome

Population studied

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

660

Study design details

Outcomes

The feasibility of undertaking routine follow up for longer term outcomes. This will be measured by the ability to recruit and retain women during their pregnancy and past their child's 2nd birthday.

Data analysis plan

Data will be analyzed investigating the feasibility and the acceptability of the LIFETIME System. Frequency information will be provided with regards to number of women recruited in specific time periods by specific groups and as a total by medication type. Rates of completion of the Ages and Stages Questionnaires at each age point, stratified by key demographic variables will be calculated. Rates of questionnaire completion and missing data will also be calculated.

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

EUPAS43300-43377.pdf(164.98 KB)

Composition of steering group and observers

EUPAS43300-45478.pdf(58.15 KB)

Data sources

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection, Exposure 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