Prediction of venlafaxine exposure through breastfeeding

First published: 02/02/2023

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Study Ongoing

Administrative details

EU PAS number

EUPAS103385

Study ID

103390

DARWIN EU® study

No

Study countries

☐ Switzerland

Study description

The exposure of infants to drugs through breastmilk can be highly variable and depends on the dose ingested by the child along with the absorption, the distribution, the metabolism and the elimination of the drug by the child.

Characterisation of this exposure is essential to provide recommendations for preventing toxicity in breastfed infants and assuring mother’s adequate treatment. This can be achieved by assessing the physicochemical and pharmacokinetic properties of the drugs and inter-individual variability due to characteristics of the mothers and breastfed infants. This study will allow suppling a European biobank located in Uppsala with samples of breast milk, from breastfeeding women taking venlafaxine provided by participants in Switzerland.

Study status

Ongoing

Research institutions and networks

Institutions

Centre Hospitalier Universitaire Vaudois (CHUV)

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Institution

Contact details

Study institution contact

Alice Panchaud alice.panchaud@chuv.ch

Study contact

alice.panchaud@chuv.ch

Primary lead investigator

Alice Panchaud

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 03/08/2021

Study start date

Actual: 03/08/2021

Date of final study report

Planned: 03/08/2023

Sources of funding

- Other

More details on funding

H2020-Grant - Innovative medicine initiative call 13 topic 9 « ConcePTION »

Study protocol

4. Protocole_Venlafaxine_20210709_v5.pdf (1.96 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Other study registration identification numbers and links

Swissethics (Swiss Ethics Committees on research involving humans) registration number : 2021-00828,https://raps.swissethics.ch/runningProjects_list.php?q=%28ProjectTitle~contains~

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

Pharmacokinetic lactation study

Main study objective:

The objective of this study is, using a PopPK modelling approach, to characterize the pharmacokinetics of venlafaxine and its active metabolite in breastfeeding women during the postpartum period.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

VENLAFAXINE

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

20

Study design details

Data analysis plan

The pharmacokinetic characterisation of the lactating women population, will be achieved through PopPK approach, that is based on non-linear mixed effect modelling techniques. These analyses will be carried out using population PK/PD parameter estimation programs such as NONMEN, MONOLIX. PopPK allows estimating both fixed (i.e. invariant) population parameters and random effects (i.e. inter-individual and residual variability) by grouping all the samples collected in the study population. PopPK will then be used to define the main pharmacokinetic parameters of venlafaxine and its active metabolite along with their variability in milk, and to study the influence of co-factors on drugs disposition in the population of lactating mothers. This approach will combine drug and O-demethylvenlafaxine data collected in milk, while integrating clinical, demographic and environmental aspects and quantifying variability between individuals.

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 sources (types)

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