Venlafaxine exposure in pregnancy, a multicenter ENTIS study

First published: 15/10/2012

Last updated: 19/04/2021

Study Ongoing

Administrative details

EU PAS number

EUPAS3057

Study ID

40624

DARWIN EU® study

No

Study countries

- Finland
- France
- Israel
- Italy
- Netherlands
- Switzerland

Study description

Introduction Venlafaxine (Efexor®) is a serotonin and noradrenaline reuptake inhibitor (SNRI) used for the treatment of depression and anxiety disorders. The limited data on the use of venlafaxine in human pregnancy do not indicate an increased risk of congenital malformations. The main purpose of the study is to assess the rate of major malformations after first trimester exposure to venlafaxine. Methods This multicenter, prospective cohort study was performed using data from eight centers who are member of the European Network of Teratology Information Services (ENTIS). Data on pregnancy and pregnancy outcome of women who used venlafaxine in pregnancy were collected during individual risk counseling. Standardized procedures for data collection and follow-up were used by each center.

Study status

Ongoing

Research institutions and networks

Institutions

Netherlands Pharmacovigilance Centre Lareb

Netherlands

First published: 05/02/2010

Last updated: 19/07/2016

Institution | Outdated | Not-for-profit | ENCePP partner

Teratology Information Service, Helsinki (TIS Helsinki), HUSLAB

Finland

First published: 09/04/2010

Last updated: 16/08/2011

Institution | Outdated | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Swiss Teratogen Information Service

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Centre de Référence sur les Agents Tératogènes (CRAT) Paris, France, Florence Teratology Information Service, Careggi university hospital Florence, Italy, CEPIG, Genetica Clinica, Azienda Ospedaliera Padov Padova, Italy, Poison Control Centre and Teratology Information Service, Ospedali Bergamo, Italy, Swiss Teratogen

Information Service and Division of clinical Pharmacology and Toxicology, University Hospital, Lausanne Lausanne, Switserland, BELTIS Rabin. Medical. Center Petah-Tikva Affiliated with the Sackler School of Medicine, Tel Aviv University Tel Aviv, Israel, Telefono Rosso, Catholic University of Sacred Heart Rome, Italy

Networks

European Network of Teratology Information Services (ENTIS)

- Austria
- Czechia
- Finland
- France
- Germany
- Greece
- Italy
- Netherlands
- Spain
- Switzerland
- United Kingdom

First published: 31/05/2010

Last updated: 13/05/2024

Network | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Bernke te Winkel

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/09/2008

Study start date

Actual: 27/10/2008

Date of final study report

Planned: 28/12/2021

Sources of funding

- Other

More details on funding

Ministery of Health, The Netherlands

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 assess the risk of venlafaxine exposure in early pregancy

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

VENLAFAXINE

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

1300

Study design details

Outcomes

Rate of major birth defects after first trimester exposure, rate of spontaneous abortionrate of prematuritybirth weightpostnatal disorders

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Data analysis plan

Birth defect rates include live births and anomalies in elective terminations of pregnancies (ETOPs) and miscarriages. For calculating rates of major birth defects possibly associated with a teratogen, welldefined genetic syndromes are excluded. See: Schaefer C, Ornoy A, Clementi M, Meister R, Weber-Schoendorfer C. Using observational cohort data for studying drug effects on pregnancy outcome--methodological considerations. Reprod Toxicol. 2008,26:36-41. For calculation spontaneous abortion rate see Meister R, Schaefer C. Statistical methods for estimating the probability of spontaneous abortion in observational studies--analyzing pregnancies exposed to coumarin derivatives. Reprod Toxicol. 2008,26:31-5

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

ENTIS provides drug risk assessment for pregnant patients and/or physicians. Exposed pregnancies are documented and after the expected date of delivery,

follow-up is conducted both using a structured questionaire or phone interview.See Schaefer C et al, Reproductive Toxicology 2008,26,36-41

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