Varenicline use in pregnancy

First published: 25/11/2015

Last updated: 29/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11672

Study ID

16556

DARWIN EU® study

No

Study countries

- [ ] Australia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Israel
- [ ] Netherlands
- [ ] Türkiye

United Kingdom

Study description

The aim of this study is to assess some of the fetal risks posed by maternal use of varenicline during pregnancy.The primary objectives are to evaluate the occurrence of congenital malformation (both major and minor) following varenicline exposure in the first trimester, spontaneous abortion (defined as spontaneous fetal loss prior to 24 weeks gestation) or intrauterine death/fetal demise or stillbirth (defined as fetal loss from 24 weeks gestation onwards). As a secondary objective we aim to perform an evaluation of the incidence of elective termination, including an assessment of the gestational age at which this occurred, and where sufficient details are available, the indication for elective termination.

Study status

Finalised

Research institutions and networks

Institutions

The UK Teratology Information Service

Networks

European Network of Teratology Information Services (ENTIS)

Austria

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

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Network **ENCePP partner**

Contact details

Study institution contact

Richardson Jonathan jonathan.richardson@nuth.nhs.uk

Study contact

jonathan.richardson@nuth.nhs.uk

Primary lead investigator

Yates Laura

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/06/2013

Actual: 01/06/2013

Study start date
Planned: 01/05/2014

Actual: 10/07/2014

Data analysis start date
Planned: 01/08/2014

Actual: 21/05/2015

Date of final study report
Planned: 05/06/2016

Actual: 05/06/2016

Sources of funding

- Other

More details on funding

Funding bodies of individual TIS within ENTIS

Study protocol

ENTIS collaborative study protocol - varenicline version 1.4 - circulated.pdf

(138.67 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

Testing the fetal effects of first trimester varenicline use in pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

VARENICLINE

Population studied

Short description of the study population

Pregnant women which were reported to the TIS whilst the pregnancy was ongoing prior to 24 weeks gestation with or without exposure to varenicline.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Pregnant women

Estimated number of subjects

434

Study design details

Outcomes

The primary aim of this study was to compare the incidence of major and minor congenital malformations between first trimester varenicline exposed pregnancy and non-exposed control pregnancies. Secondary aims included comparison of the spontaneous abortion, elective termination and intrauterine death rates.

Data analysis plan

We will compare the rate of major and minor malformations between exposed and control pregnancies primarily using non-parametric methods (due to small sample size), and where possible include some adjustment for confounding variables using parametric methods (logistic regression). The cumulative incidences of spontaneous abortion, intrauterine death and elective termination will be compared using time dependent cox proportional hazards models. Where possible, adjustment for confounding variables will be undertaken.

Documents

Study publications

Richardson, J.L., S. Stephens, L.M. Yates, O. Diav-Citrin, J. Arnon, D. Beghin,...

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

Unknown