Vedolizumab-5001: Organization of Teratology Information Specialists (OTIS) Vedolizumab Pregnancy Exposure Registry

First published: 08/01/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS11681

Study ID

49443

DARWIN EU® study

No

Study countries

- ☐ Canada
- ☐ United States

Study description

This is a prospective, multicenter observational cohort study of pregnant women with ulcerative colitis (UC) and Crohn's disease (CD),who are at least 1 dose exposed at any time from last menstrual period (LMP) during pregnancy to vedolizumab (Entyvio) or other biological agents for UC or CD. The purpose of this study is to monitor planned and unplanned pregnancies in UC or CD female patients exposed to vedolizumab and to evaluate any possible association between this medication and pregnancy outcome, including the health of the mother, fetus, and infant. The study population of pregnant women would be drawn from 3 sources: OTIS Network, pregnant women who spontaneously contact the study research center or the sponsor or who are referred by their health care practitioners (HCP) in North America and women in North America who become pregnant while participating in other Entyvio clinical studies being undertaken by the sponsor. The planned total duration of the study is 6 years and cohort enrollment will be done before 20 weeks of gestation period and intake interviews would be scheduled telephonically. If subject is enrolled and intake interview is conducted between 16 and 20 week’s gestation, only one interim interview will be conducted during pregnancy at 32-34 week’s gestation. Outcome interview would be conducted within 0 to 6 weeks after delivery, dysmorphological examination of live infants would be conducted within 0 to 12 months after delivery and pediatric medical record review and questionnaire would be held 1 year after delivery.

Study status

Finalised

Research institutions and networks

Institutions

Organization of Teratology Information Specialists (OTIS)

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Institution

Contact details

Study institution contact

Christina Chambers trialdisclosures@takeda.com

Study contact

trialdisclosures@takeda.com

Primary lead investigator

Christina Chambers

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/10/2015

Actual: 20/11/2015

Study start date

Planned: 30/10/2015

Actual: 01/12/2015

Data analysis start date
Planned: 01/12/2022

Date of final study report
Planned: 30/06/2023

Actual: 02/06/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

Vedolizumab-5001 Protocol Version 1 2015-10-05.pdf(690.15 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

The primary objective of the study is to assess the prevalence of major structural birth defects in infants of women with UC or CD exposed to vedolizumab during pregnancy, compared to women with UC or CD exposed to other biologic agents.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

ENTYVIO

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

VEDOLIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AA33) vedolizumab

vedolizumab

Medical condition to be studied

Colitis ulcerative

Crohn's disease

Population studied

Age groups

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

300

Study design details

Outcomes

Primary outcome included the major structural defects (either cosmetic or functional significance to the child) identified after infant's birth up to 1 year of age. Secondary outcome included the minor structural defects (neither cosmetic or functional significance to the child) identified through dysmorphology examination after infant's birth up to 1 year of age.

Data analysis plan

Primary analysis between the vedolizumab-exposed group and the other biologic agents-exposed group will use Fisher exact test for univariate comparisons and logistic regression for multivariate analysis with adjustment for confounders.

Documents

Study results

Final OTIS Entyvio Analysis Report_02June2023.pdf(161.9 KB)

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)

Disease registry

Electronic healthcare records (EHR)

Other

Pregnancy registry

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