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

First published: 08/01/2016

**Last updated:** 21/11/2024





### 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)

First published: 01/02/2024

**Last updated:** 01/02/2024

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

#### **Medicinal product name**

**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

# 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