

# Vedolizumab-4020: A Multicenter, Single-arm, Open-label, Phase 4 Study to Evaluate the Safety and Efficacy of Vedolizumab in Indian Patients With Ulcerative Colitis and Crohn's Disease

**First published:** 10/09/2018

**Last updated:** 22/01/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS23702

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### Study ID

45304


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### DARWIN EU® study

No

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### Study countries

 India

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## Study description

Vedolizumab is a medicine that helps to reduce sensitivity and pain in the digestive system. In this study, people with ulcerative colitis or Crohn's disease will be treated with vedolizumab. The main aim of the study is to check for side effects from Vedolizumab. At the first visit, the study doctor will check who can take part. Participants will receive vedolizumab slowly through a vein (infusion). Participants will regularly visit the clinic for up to 46 weeks for more infusions of Vedolizumab. During these visits, the study doctor will check if there are any side effects from this treatment. Participants will visit the clinic for a final check-up up to 16 weeks after their final infusion of Vedolizumab. Clinic staff will arrange a phone call 6 months after their final infusion of Vedolizumab for a further check-up.

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## Study status

Finalised

## Research institutions and networks

### Institutions

**Takeda**

**First published:** 01/02/2024

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

**Institution**

Osmania General Hospital, Hyderabad, India,  
Sunshine Institute for Gastroenterology, Liver  
Diseases and Minimal Invasive Surgery,  
Telangana, India, Shree Giriraj Multispeciality  
Hospital, Surat Institute of Digestive Sciences,  
Apollo Hospital International Ltd Gujarat, India,  
Post Graduate Institute of Medical Education and  
Research (PGIMER) Chandigarh, India, Indira  
Gandhi Institute of Medical Sciences Bihar, India,  
Gandhi Hospital Secunderabad, India, Lakeshore  
Hospital and Research Centre Ltd, Aster Medcity,  
Aster DM Healthcare Pvt Ltd, Amrita Institute of  
Medical Sciences Kerala, India, VGM Hospital,  
Institute of Gastroenterology Coimbatore, India,  
Institute of Medical Gastroenterology (IMG).  
Madras Medical College & Rajiv Gandhi  
Government General hospital Chennai, India,  
Midas Multispeciality Hospital Pvt. Ltd.  
Maharashtra, Institute of Digestive and Liver

Disease Dispur Hospitals, Assam, Dayanand  
Medical college and Hospital, Punjab, Peerless  
Hospitex Hospital and Research Centre Ltd.  
Kolkata, India

## Contact details

### Study institution contact

Sandeep Arora [trialdisclosures@takeda.com](mailto:trialdisclosures@takeda.com)

Study contact

[trialdisclosures@takeda.com](mailto:trialdisclosures@takeda.com)

### Primary lead investigator

Singh Inderjeet

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 31/03/2021

Actual: 01/09/2017

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### Study start date

Planned: 30/11/2021

Actual: 29/12/2021

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### **Data analysis start date**

Planned: 31/10/2023

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### **Date of final study report**

Planned: 28/02/2024

Actual: 04/10/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Takeda

## Study protocol

[Vedolizumab-4020-clinical-study-protocol-redact.pdf](#) (1.6 MB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Clinical trial

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Main study objective:**

The main objective of the study is to assess the safety and effectiveness of vedolizumab intravenously (IV) in participants with UC or CD in India.

## Study drug and medical condition

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

VEDOLIZUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(L04AA33) vedolizumab

vedolizumab

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**Medical condition to be studied**

Inflammatory bowel disease

Colitis ulcerative

Crohn's disease

## Population studied

## Age groups

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
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## Estimated number of subjects

150

# Study design details

## Outcomes

To assess the safety of vedolizumab IV in participants with UC or CD in India the primary endpoint includes: Incidence of adverse events (AEs), serious AEs (SAEs), AEs of special interest (AESIs), adverse drug reactions (ADRs), and unexpected ADRs. To assess the efficacy of vedolizumab IV in participants with UC or CD in India the secondary endpoints include: Proportion of participants with clinical response, clinical remission, vedolizumab discontinuation and mucosal healing/endoscopic response, Change in the patient-reported Quality of Life (Short Inflammatory Bowel Disease Questionnaire) from Baseline.

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## Data analysis plan

For assessment of primary outcome measure, exposure-adjusted incidence rates and 95 percent (%) confidence intervals (Cis) will be calculated based on total numbers of incident events and person-time at risk. Two separate incidence calculations will be used: incidence rates for events that occur while on vedolizumab therapy, and incidence rate for events that occur after discontinuation of vedolizumab. Descriptive summaries will be provided for effectiveness outcomes too.

## Documents

## Study results

[Vedolizumab-4020-clinical-study-report-redact.pdf](#) (1.47 MB)

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## 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](#)

[Other](#)

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### 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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No