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

Study ID

45304

DARWIN EU® study

No

Study countries

☐ India

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.

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 Multispecality 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

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Study contact

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Primary lead investigator

Singh Inderjeet

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/03/2021

Actual: 01/09/2017

Study start date

Planned: 30/11/2021

Actual: 29/12/2021

Data analysis start date
Planned: 31/10/2023

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Clinical trial

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

Anatomical Therapeutic Chemical (ATC) code

(L04AA33) vedolizumab

vedolizumab

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)

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.

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)

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

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

No