A Swedish Observational Study on Vedolizumab Assessing Effectiveness And Healthcare Resource Utilization in Patients with Inflammatory Bowel Disease (IBD) (SVEAH)

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Study Finalised

Administrative details

EU PAS number

EUPAS22735

Study ID

42810

DARWIN EU® study

No

Study countries

Sweden

Study description

This is a prospective, multi-center, observational and cohort study for patients with IBD. This study will assess the effectiveness of vedolizumab for achieving clinical response at Week 12 and remission at Week 52 in participants with confirmed and active disease of ulcerative colitis (UC) and Crohn’s disease (CD), and will assess the long term effectiveness of vedolizumab treatment among 3 months responders or remitters in clinical practice. Patients that are initiated on treatment with vedolizumab will be recruited into the cohort. Patients may either be naive to biologic treatment or may have previous experience with biologic treatment. Patients must not have previous experience with vedolizumab at entry. The study will have two phases: Phase 1 and Phase 2. Phase 1 will enrol approximately 300 participants (125 participants with UC and 175 with CD) in a cohort who have initiated a treatment with vedolizumab in a clinical practice. Participants from Phase 1 who will be on vedolizumab treatment at Week 52 will be asked to continue in Phase 2. This study will be conducted at approximately 20 sites in Sweden. The data will be collected for up to 52 weeks in Phase 1 and for up to 156 weeks in Phase 2 of this study.

Study status

Finalised

Research institutions and networks

Institutions

Department of Medicine, Karolinska University hospital, Department of Gastroenterology, Linköping University hospital, Department of

Gastroenterology, Skånes University hospital Lund, Department of Gastroenterology, Akademiska university hospital Uppsala, Department of Gastroenterology, Skånes University Malmö, Department of Medicine, Falun hospital, Department of Gastroenterology, Sahlgrenska University hospital, Department of Gastroenterology, Norra Älvsborgs hospital Trollhättan, Department of Medicine, Norrlands University hospital, Department of Gastroenteroloigy, Ryhov's hospital Jönköping, Department of Medicine, Sunderby hospital, Department of Internal Medicine, Södra Älvsborg hospital Borås, Department of Gastroenerology, Ersta diakoni hospital, Department of Internal Medicine, Skaraborgs hospital Lidköping, Department of Gastroenterology, Danderyd's hospital, Department of Gastroenterology, Västerås hospital, Department of

Gastroenterology, Södersjukhuset, Department of Internal Medicine, Hallands hospital Kungsbacka, Department of Internal Medicine, Capio S:t Görans hospital, Department of Medicine, Hallands hospital Halmstad

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jonas Halfvarson

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/03/2015

Study start date

Actual: 01/06/2015

Data analysis start date
Actual: 01/09/2020

Date of final study report
Planned: 01/09/2021

Actual: 01/09/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda Pharma AB

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:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective of Phase 1 is to assess the effectiveness of vedolizumab for achieving clinical response at Week 12 and remission at Week 52, and of Phase 2 is to assess long-term effectiveness among 3 months responders/remitters of vedolizumab treatment in clinical practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

Medical condition to be studied

Crohn's disease

Colitis ulcerative

Inflammatory bowel disease

Population studied

Short description of the study population

Eligible patients were ⩾18years old and had active IBD at the onset of vedolizumab. Active Crohn’s disease was defined as presence of symptoms based on patient reported outcome measures in combination with ulcers at colonoscopy, signs of active disease at magnetic resonance imaging (i.e. contrast enhancement, bowel thickening or combs sign), C-reactive protein (CRP) higher than the lower limit of detection, high-sensitivity CRP >2.87mg/l or faecal calprotectin >200µg/g not more than 4weeks before onset of treatment. The lower limit of detection defines normal CRP concentration in clinical practice. According to the manufacturers, the threshold was 4.0mg/l for most CRP assays. Correspondingly, active ulcerative colitis was defined as the presence of symptoms accompanied by a Mayo endoscopic subscore of ⩾2 not more than 4weeks before initiation of vedolizumab.

Exclusion criteria were concurrent participation in a clinical trial in which IBD treatment was dictated by an (interventional) study protocol, contraindications to vedolizumab (i.e. patients with known hypersensitivity to vedolizumab or any of its excipients), prior exposure to vedolizumab or planned cessation of treatment within 12months from initiation (e.g. planned pregnancy). Written informed consent was obtained from all individual participants included in the study. Vedolizumab therapy was initiated according to its summary of product

characteristics, that is, at a dose of 300mg at weeks 0, 2 and 6, followed by 300mg every 8weeks. Patients with Crohn’s disease who had not responded by week 10 were allowed to receive an additional dose at week 10. However, as this was an observational study, the treating physician was permitted to adjust the dose or dosing interval at any time.

Age groups

- 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

Other

Special population of interest, other

Patients with Crohn's disease, Colitis ulcerative, Inflammatory bowel disease

Estimated number of subjects

300

Study design details

Outcomes

Primary outcome for Phase 1 is clinical response at Week 12 and clinical remission at Week 52 in participants with UC or CD. Primary outcome for Phase 2 is long term remission among 3 months responders/remitters in participants with UC based on partial mayo score (PMS) and in participants with CD based

on Harvey Bradshaw Index (HBI) at Week 104 and 156, Clinical remission(Week 12),clinical response(Week 52),corticosteroid free remission,time off corticosteroids rate,Long term effectiveness,sustained long-term remission in 3 months,drug continuation rates, B-Hemoglobin,P-CRP and f-calprotectin,long-term corticosteroid free remission,quality of life,change in presence of extraintestinal manifestations,healthcare resources, adverse-drug reactions.

Data analysis plan

The primary analysis will be performed following the intention to treat principle, where missing data are assumed to represent treatment failure. Where up to two items are missing for the short health scale (SHS) and EQ-5D-5L, these measures will be imputed to the mean value. The potential influence of including imputed data will be assessed by sensitivity analyses where those with any missing data for these measures are excluded.

Documents

Study results

Vedolizumab-5008_Results Publication.pdf (568.82 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)

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