Vedolizumab-4081: Infection Outcomes among Advanced Therapy-naive Older Adult US Patients With UC/CD Initiating ENTYVIO, TNF-alpha Inhibitors, or Ustekinumab: A Retrospective Observational Matched-Cohort Study Using Medicare Claims Data, 2016-2025

First published: 17/12/2025

Last updated: 19/01/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000767

Study ID

1000000767

DARWIN EU® study

No

Study countries

United States

Study description

More older people (more than 65 years of age) around the world are getting Ulcerative Colitis (UC) or Crohn’s Disease (CD). This is happening because people are living longer and because more people overall are developing Ulcerative Colitis (CD) or Crohn’s Disease (CD). Medicines that treat UC/CD, however, might make it easier for older adults to get infections.

The main aim of this study is to learn if there is a difference in the number and type of infections in older people when treated with either ENTYVIO or other advance medicines (called TNF-alpha inhibitors or ustekinumab) that reduce swelling and pain by blocking a chemical in the body (called TNF-alpha).

The study will include people aged 65 years and older with UC or CD who used either ENTYVIO or a TNF-alpha inhibitor or ustekinumab between 2016 and 2025.

Data will be collected from existing Medicare databases.

Study status

Ongoing

Research institutions and networks

Institutions

Takeda

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Study Contact Takeda TrialDisclosures@takeda.com

Study contact

TrialDisclosures@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/02/2025

Study start date

Planned: 15/12/2025

Actual: 15/12/2025

Date of final study report

Planned: 31/03/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

Vedolizumab-4081-clinical-study-protocol-redact.pdf (1.73 MB)

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

A retrospective, observational, matched-cohort study design will be employed using 100% sourced Medicare FFS secondary claims data from Parts A and B, standalone Part D PDE data to assess safety outcomes.

Main study objective:

The main aim of this study is to learn if there is a difference in the number and type of infections in older people when treated with either ENTYVIO or other advance medicines (called TNF-alpha inhibitors or ustekinumab) that reduce swelling and pain by blocking a chemical in the body (called TNF-alpha).

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

USTEKINUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AG05) vedolizumab

vedolizumab

(L04AC05) ustekinumab

ustekinumab

(L04AB) Tumor necrosis factor alpha (TNF-alpha) inhibitors

Tumor necrosis factor alpha (TNF-alpha) inhibitors

Medical condition to be studied

Colitis ulcerative

Crohn's disease

Population studied

Short description of the study population

United States (US) adult participants diagnosed with UC or CD who initiated ENTYVIO or other advanced medical therapies (AMTs) will be included in this study.

Age groups

- **Adult and elderly population (≥18 years)**
  - Elderly (≥ 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

Ulcerative Colitis or Crohn’s Disease

Estimated number of subjects

23900

Study design details

Outcomes

The primary outcomes will assess the percentage of participants hospitalized due to serious infections over a period of up to 4 months.

The secondary outcomes will assess the percentage of participants who experience non-serious infections over a period of up to 4 months.

Data analysis plan

The statistical analysis of the data will be primarily descriptive. Continuous variables will be reported using means, medians, standard deviations (SD), and interquartile ranges (IQRs). Categorical variables will be reported as frequencies and percentages.

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 source(s), other

Medicare Claims

Data sources (types)

Administrative healthcare records (e.g., claims)

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