Incidence of Surgical Site Infections After Lower Gastrointestinal Surgery in Patients With Crohn’s Disease or Ulcerative Colitis

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/34269

EU PAS number

EUPAS16564

Study ID

34269

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is a non-interventional retrospective cohort study. The drug being tested in this study is called vedolizumab. This study will look at the incidence of surgical site infections (SSI) after a lower GI surgery in patients with CD or UC, and determine if it varies by type of inflammatory bowel disease (IBD) therapy. Participants will be identified for participation in the study through Optum Clinformatics Data Mart, which is a database managed by the United States started in May 2000. Participants who have CD or UC and underwent a major lower GI surgery after 01 September 2014 will be identified from the database. Participants will be assessed for infections such as postoperative wound infection, peritonitis, retroperitoneal infection, and sepsis occurring 2-30 days after the lower GI surgery.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Huifang Liang

Study contact

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Primary lead investigator

Huifang Liang

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/12/2016

Actual: 20/12/2016

Study start date

Planned: 20/12/2016

Actual: 20/12/2016

Data analysis start date

Planned: 20/01/2017

Actual: 30/09/2017

Date of final study report

Planned: 31/12/2017

Actual: 30/12/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda Ltd

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

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To quantify incidence of surgical site infections (SSI) after lower GI surgery in patients with UC or CD on non-biologic therapy, anti-tumor necrosis factor-alpha (TNF-alpha)/ustekinumab therapy, and vedolizumab therapy and to identify risk factors for SSIs after lower GI surgery in patients with UC or CD.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Crohn's disease

Colitis ulcerative

Population studied

Short description of the study population

Adults with ulcerative colitis (UC) or Crohn’s disease (CD) who underwent lower gastrointestinal (GI) surgery of small intestine, colon, rectum, or anus during September 2014 to September 2016.

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

Immunocompromised

Estimated number of subjects

2000

Study design details

Outcomes

Incidence of surgical site infections (SSI) occurring 2-30 days after the surgical procedure after 1 September 2014.

Data analysis plan

Cumulative incidence (per 100 patients) of SSI will be calculated overall and for drug exposure categories (vedolizumab, anti-TNF-alpha anti-tumor necrosis factor- alpha/ustekinumab, and conventional therapy). A multivariate logistic regression model will be contructed to identify risk factors for an SSI, with the exposure reference group being conventional therapy. A stepwise regression will be used to fit covariates with a $p<0.1$ to enter a covariate and a $p<0.05$ to remain a covariate in the model.

Documents

Study results

Vedolizumab-5030 - Article.pdf(168.42 KB)

Data management

Data sources

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