Herpes zoster and other opportunistic infections in patients with inflammatory bowel disease in Norway – associations with immunosuppressive treatment (NOZOIBD)

First published: 03/07/2020

Last updated: 02/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/44561

EU PAS number

EUPAS36045

Study ID

44561

DARWIN EU® study

No

Study countries

Norway

Study description

Due to extenuating business circumstances based on availability of data and resources Pfizer will not be pursuing this study. Study is officially cancelled on 30 November 2021. Patients with inflammatory bowel disease (IBD), i.e. ulcerative colitis or Crohn’s disease are treated with immunosuppressive drugs that increases their risk of infections, including herpes zoster (HZ) and other opportunistic infections (OI). This non-interventional retrospective observational study aims to quantify rates of HZ and other OI, including the association with immunosuppressive treatment, in Norwegian IBD patients.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Edith Owens

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/01/2020

Actual: 24/01/2020

Study start date

Planned: 01/02/2022

Actual: 30/11/2021

Date of final study report

Planned: 01/06/2023

Actual: 30/11/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921367_PROTOCOL and APPROVAL_V1.0_04MAY2020.pdf(2.45 MB)

A3921367_Non-Interventional Study Protocol Amendment 1_V2.0_30MAR2021.pdf(2.56 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

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:

The project aims to quantify the burden of herpes zoster and other opportunistic infections (i.e. incidence rates and rate of complications), including the association with immunosuppressive treatment, in Norwegian patients with inflammatory bowel disease.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

TOFACITINIB

INFLIXIMAB

Medical condition to be studied

Crohn's disease

Colitis ulcerative

Population studied

Short description of the study population

The study population includes all patients in Norway registered with IBD (ICD code K50 or K51) and aged ≥18 years in NPR in the time period between 2008 and 2019 that do not meet any exclusion criteria

Inclusion Criteria

All patients who are registered with at least 1 diagnosis of IBD (ICD-code K50 or K51) and aged ≥18 years in NPR during the study period 2008-2019.

Exclusion Criteria

Patients meeting any of the following criteria will not be included in the study:

1. A single hospital discharge diagnosis of IBD (ICD-code K50 or K51) and no pharmacy claim for IBD medication (eg, 5-ASA, thiopurines, anti-TNF, enteral budesonide) (indicates that initial diagnosis of IBD was wrong).
2. Diagnosis of HIV-infection (ICD B25, R75), cancer (ICD C00-C97), organ transplantation (ICD Y830) or congenital immunodeficiency (ICD D80-D84) (confounds the study since these are independently associated with increased risk of HZ and other OI).

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

Estimated number of subjects

55000

Study design details

Outcomes

The incidence rate of HZ, including the rate of recurrent events, rates of disseminated HZ and complications (e.g. postherpetic neuralgia) and the incidence rate of other OI (e.g. C. difficile, CMV, fungal infections) in Norwegian IBD patients. • The association between medical treatment (glucocorticoids, thiopurine, methotrexate, anti-TNF, anti-TNF+thiopurine, vedolizumab, ustekinumab and tofacitinib) and incidence of HZ and other OI. • The proportion of HZ events in IBD patients managed in general practice vs in hospitals. • The proportion of IBD patients that are receiving anti-viral therapy for HZ events.

Data analysis plan

Categorical variables will be described with the number of values, percentages and as incidence rate/1000 patient years. Data will also be calculated according to age categories. To assess the association between medical treatment (glucocorticoids, thiopurines, methotrexate, anti-TNF, anti-TNF+thiopurine, vedolizumab, ustekinumab and tofacitinib) and incidence of HZ or other OI, we will do a Cox regression with both fixed and time-dependent covariates. This entails following the patients from their first IBD diagnosis to their first diagnosis of HZ or other OI, adjusting for other covariates (age, gender,

treatment both current and prior). Results will be presented as multivariable adjusted hazard ratios and survival plots.

Data management

Data sources

Data source(s), other

NorPD

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

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