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

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## Administrative details

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

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Institution

## Contact details

## Study institution contact

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**Study contact** 

## **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  $\geq$ 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)</li>
- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)</li>
- Adults (75 to < 85 years)
- Adults (85 years and over)

#### Special population of interest

Other

### Special population of interest, other

#### **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

## **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

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