Is Intravenous Bisphosphonate Use Associated with a Higher Risk of a Flare in Inflammatory Bowel Disease Patients? (Bisphosphonates and IBD Flare Risk)

First published: 02/11/2019

Last updated: 02/08/2020

Study Ongoing

Administrative details

EU PAS number

EUPAS32010

Study ID

36589

DARWIN EU® study

No

Study countries

United States

Study description

Specific Aims: 1. To describe patients with inflammatory bowel disease that are being treated with intravenous and oral bisphosphonate therapyHypothesis: We hypothesize that the majority of IBD patients treated with bisphosphonates are older and receive oral bisphosphonates2. To determine if intravenous bisphosphonate therapy is associated with an increased risk of flare of IBD activity, as measured by a new prescription for a corticosteroid or an IBD-related emergency room visit or hospitalization, compared with oral bisphosphonate therapy Hypothesis: We hypothesize that intravenous bisphosphate therapy will be significantly associated with a flare of disease activity

Study status

Ongoing

Research institutions and networks

Institutions

University of North Carolina at Chapel Hill

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jeff Yang

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/11/2019

Actual: 02/11/2019

Study start date

Planned: 02/11/2019

Actual: 02/11/2019

Data analysis start date

Planned: 02/11/2019

Actual: 02/11/2019

Date of final study report

Planned: 31/12/2020

Sources of funding

- Other

More details on funding

National Institutes of Health, Royster Society of Fellows

Study protocol

Protocol final submitted_20191101.pdf (208.44 KB)

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To describe bisphosphonates use patterns among patients with inflammatory bowel disease, and to compare risk of IBD flare between users of intravenous bisphosphonates vs. oral bisphosphonates.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(M05BA) Bisphosphonates

Bisphosphonates

Medical condition to be studied

Inflammatory bowel disease

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

10.000

Study design details

Outcomes

The primary outcomes are surrogate markers of flares of IBD activity, in the 30 days following bisphosphonate use1. IBD-related emergency room visit2. IBD-related hospitalization3. Systemic corticosteroid or enteral budesonide prescription in those who were not treated with corticosteroids in the 30 day period before the index date

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Data analysis plan

Analysis1. After identifying the IBD Cohort, we will compare the demographics, such as age, sex, geographic location and Charlson co-morbidity index, as well as available disease related variables, such as type of IBD, medications used in the 90 days prior to bisphosphonate use, IBD related hospitalizations, surgery and health care utilization of IBD patients using IV versus oral bisphosphonates2. We will construct a propensity score model to compare IBD patients receiving IV bisphosphonates to those receiving oral bisphosphonates. We will implement standardized mortality ratio (SMR) weighting using estimated propensity scores to achieve covariate balance between the IV and oral bisphosphonate cohorts, to control for measured confounding. The estimand of interest will be the average treatment effect among the treated (IV bisphosphonates users).3. We will compare the crude and adjusted 30-day incidence of outcomes in the IV bisphosphonate group and oral bisphosphonate group.

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)

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