Observational study on the risk of myocardial infarction and stroke associated with proton pump inhibitor use (RiDe-PPI (MI & STROKE))

First published: 27/09/2019

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS31559

Study ID

45320

DARWIN EU® study

No

Study countries

☐ Germany

Study description

This study is using ten years of claims database records provided by the largest statutory health insurance provider in Bavaria to estimate the effect of long-term intake of proton pump inhibitors on the risk of acute myocardial infarction and ischaemic stroke in adults. Our approach uses routinely collected health care data to conduct an observational study that emulates a clinical trial using clear inclusion criteria, period of enrolment, active treatment phases, and long-term follow up. The results of this study will provide additional evidence on the relationship between PPI use and the risk of myocardial infarction and stroke.

Study status

Finalised

Research institutions and networks

Institutions

Ludwig-Maximilians-University Munich

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sebastian-Edgar Baumeister

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/12/2018

Actual: 11/12/2018

Study start date

Planned: 01/10/2019

Actual: 01/10/2019

Date of final study report

Planned: 31/03/2021

Actual: 03/09/2021

Sources of funding

- Other

More details on funding

Innovationsausschuss beim G-BA (Gemeinsamer Bundesausschuss)

Study protocol

20190926_RiDe-PPI_(MI_STROKE)_Study_Protocol_(v1.0).pdf(258 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

https://innovationsfonds.g-ba.de/projekte/versorgungsforschung/ride-ppi-gesundheitliche-risiken-und-determinanten-der-dauereinnahme-von-protonenpumpeninhibitoren.213

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

Data collection methods:

Secondary use of data

Main study objective:

We investigate whether long-term intake of proton pump inhibitors is associated with the risk of myocardial infarction and stroke.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A02BC) Proton pump inhibitors

Proton pump inhibitors

Medical condition to be studied

Acute myocardial infarction

Ischaemic stroke

Population studied

Short description of the study population

All patients aged 18 years or older who have been insured by the statutory health insurance provider Allgemeine Ortskrankenkasse (AOK) Bayern, for at least 2 years since January 2008.
Eligibility/exclusion criteria are: age of at least 18 years; no prevalent cardiovascular disease; no prior use of any PPIs. Additionally we demand no prior use of the
comparator medication in target trial.

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)

Estimated number of subjects

6100000

Study design details

Outcomes

The risk of myocardial infarction and stroke associated with the long-term intake of proton pump inhibitors.

Data analysis plan

|| Estimation of the observational analog of the intention-to-treat effect: We will fit pooled logistic regression models to estimate hazard ratios and survival curves using time-varying stabilized inverse-probability weights. || Estimation of the observational analog of the per-protocol effect: We will apply different

prespecified dose-response models, and derive another dose-response model from the data estimating a weighted cumulative exposure model. For each of these models we fit marginal structural Cox models using stabilized inverse probability of treatment weights.

Documents

Study publications

Nolde, M., Ahn, N., Dreischulte, T., Rückert-Eheberg, I.-M., Güntner, F., Günte...

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)

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