A cohort study with a nested case control analysis on the association between acid-suppressing drugs and seizures using THIN database in the UK (Acid suppressing Drug Seizure Epidemiology Study)

First published: 08/03/2017

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17954

Study ID

18587

DARWIN EU® study

No

Study countries

Spain

Study description

In this observational study (NCT01744301), patients aged 20–84 years in 2005–2011 were identified from The Health Improvement Network. The relative risk of seizure associated with use of proton pump inhibitors (PPIs) and histamine-2 receptor antagonists (H2RAs) in a general population was quantified, overall and stratified by epilepsy status, and the effects of demographics and comorbidities were determined. In a nested case–control analysis, seizure cases were matched to controls. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated using unconditional logistic regression. Estimates were adjusted for potential confounders.

Study status

Finalised

Research institutions and networks

Institutions

Fundación Centro Español de Investigación Farmacoepidemiológica (CEIFE)

Spain

First published: 15/03/2010

Last updated: 15/02/2024

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

Luis Alberto García Rodríguez
ClinicalTrialTransparency@astrazeneca.com

Study contact

ClinicalTrialTransparency@astrazeneca.com

Primary lead investigator

Luis Alberto García Rodríguez

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 13/12/2011

Study start date
Actual: 22/03/2013

Data analysis start date
Actual: 21/12/2014

Date of final study report
Actual: 15/05/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

D9612N00017_Redacted_protocol.pdf (362.79 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Other study registration identification numbers and links

D9612N00017

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

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:

To quantify the relative risk of seizure associated with the use of proton pump inhibitors (PPIs) and histamine-2 receptor antagonists (H2RAs) in a general population, overall and stratified by epilepsy status

Study Design

Non-interventional study design

Case-control

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A02BA) H2-receptor antagonists

H2-receptor antagonists

(A02BC) Proton pump inhibitors

Proton pump inhibitors

Medical condition to be studied

Seizure

Clonic convulsion

Convulsion in childhood

Tonic convulsion

Neonatal seizure

Febrile convulsion

Convulsions local

Population studied

Short description of the study population

Individuals aged 20–84 years identified from THIN database from 1 January 2005 to 31 December 2011, who have been enrolled with their Primary Care Physician (PCP) for at least 2 years and have a computerized prescription history of at least 1 year. Patients will have to be free of acid-suppressing drugs (PPI or H2RAs) for at least one year, and never have a diagnosis of cancer, alcohol abuse or alcohol-related disease, or drug abuse.

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

48.605

Study design details

Outcomes

To assess whether the use of acid-suppressive drugs in a general population is associated with increased risk of seizure, both overall and stratified by epilepsy status. A further aim was to determine the effects of demographic and lifestyle factors, comorbidities, and other medications on the risk of seizures

Data analysis plan

The incidence of seizure was calculated in the entire study cohort and also separately for men and women and for those with epilepsy and without. Odds ratios (ORs) and their 95% confidence intervals (CIs) were calculated using unconditional logistic regression models in order to determine the association between the use of PPIs, H2RA and other medications, comorbidities and lifestyle factors, and the occurrence of seizure. Estimates were adjusted for demographic characteristics, lifestyle factors, the most relevant comorbidity, and determinants of acute seizure.

Documents

Study publications

Sáez ME, González-Pérez A, Gaist D, Johansson S, Nagy P, García Rodríguez LA. R...

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)

THIN® (The Health Improvement Network®)

Data sources (types)

Electronic healthcare records (EHR)

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

Unknown