Triptan use and serious vascular events in elderly over 65 years (TRUE)

First published: 22/06/2015

Last updated: 12/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8976

Study ID

27270

DARWIN EU® study

No

Study countries

France

Study description

Triptans have improved the quality of life of acute migraine by providing higher efficacy and a more favorable profile of adverse drug reactions than ergotamine. Even though triptan are not recommended in older patients (over

65 years), some drug utilization studies have shown that older patients account for 5% to 10% of triptan users. To our knowledge, no specific vascular safety study has been performed among older patients exposed to triptan. The main objective of the TRUE study is to compare the incidence of cardiovascular events between a population of older triptan users (age > 65 years) and a control population. The study design is a retrospective comparative cohort study (exposed versus unexposed). We will use data from the French National Health Insurance information system (SNIIRAM) linked with the French Hospital discharge database (PMSI). We will include patients aged over 65 years, who are registered in SNIIRAM. For the exposed cohort, we will only include incident users of triptans. Exposed and unexposed cohorts will be matched (1:4 ratio) according to age, gender and area of residence. The events of interest are cardio-vascular events, death from all causes, and death related to a cario-vascular event. Data will be analyzed using Cox proportional hazards models, taking into account confounders.

Study status

Finalised

Research institutions and networks

Institutions

Department of Clinical Pharmacology and Pharmacosurveillance, University Hospital of Marseille

France

First published: 12/12/2011

Last updated: 15/07/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Pharmacologie En Population cohorteS biobanqueS (PEPSS), Hopitaux de Toulouse

France

First published: 31/03/2022

Last updated: 01/07/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Contact details

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Study contact

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Primary lead investigator

Joëlle Micallef

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 18/10/2013

Study start date
Planned: 01/06/2015

Actual: 01/11/2015

Data analysis start date
Actual: 10/01/2016

Date of interim report, if expected
Actual: 20/12/2017

Date of final study report
Planned: 01/09/2017

Actual: 20/12/2017

Sources of funding

- National competent authority (NCAs)

More details on funding

ANSM

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:

Herbal medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

To assess the risk of cardiovascular events associated with triptan exposure among patients aged 65 years and older.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02CA) Ergot alkaloids

Ergot alkaloids

(N02CC) Selective serotonin (5HT1) agonists

Selective serotonin (5HT1) agonists

Population studied

Age groups

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Study design details

Outcomes

The main outcome will be the first cardiovascular event leading to a hospitalization within the exposure period following the first dispensation of a triptan. The secondary outcomes will be all-cause death and cardiovascular-related death.

Data analysis plan

Hazard ratio for cardiovascular events using a Cox proportional hazard model with covariates. Patients will be followed-up for 90 days after their inclusion in the cohort, and HR will be calculated based on this follow-up duration. A

sensitivity analysis will be performed for other durations of follow-up (30 days, 90 days, 180 days). Covariates will be CMU, diabetes mellitus, COPD, dyslipidemia, hypertesion, and history of cardiovascular disease. Same approach will be performed for death (all-cause death and cardiovascular-related death). Nested case-control study will allow to study the association between triptan abuse and the onset of cardiovascular events. A logistic regression will be performed to compare the risk of cardiovascular events, all-cause death and cardiovascular-related death between patients unexposed to triptans and patients overusing triptans.

Documents

Study publications

Triptan Use and Serious Cardiovascular Events In Elderly Over 65 Years In Franc...

CO - 030: Triptan use and serious cardiovascular events in elderly over 65 year...

Triptan use in elderly over 65 years and the risk of hospitalization for seriou...

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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

EUPAS8976-10008.pdf (865.43 KB)

Composition of steering group and observers

Composition of steering group and Observers document.pdf (21.6 KB)

Signed code of conduct

2015-0030-Code of conduct declaration-SDPP-8976.pdf (317.36 KB)

Signed code of conduct checklist

2015-0030-Code of conduct checklist-SDPP-8976.pdf (1.63 MB)

Signed checklist for study protocols

2015-0030-Checklist for study protocols-SDPP-8976.pdf (738.53 KB)

Data sources

Data source(s)

Système National des Données de Santé (French national health system main database)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes