TRiptan Use and serious vascular events in Elderly over 65 years (TRUE)

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Study Ongoing

Contact details

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PURI

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 a higher degree of efficacy and a more favorable side effect profile than ergotamine. Even though triptan are not recommended in older patients (over 65 years), some utilization studies show 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 TRUE study is to compare the incidence of cardiovascular events between a population of older (age > 65 years) triptan users and a control population. The study design is a French comparative retrospective cohort study (exposed cohort vs. unexposed cohort). 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 i) cardio-vascular events, ii) death from all causes and death related to a cardio-vascular event. Data will be analyzed using Cox proportional hazards models, taking into account confounders.

Study status
Ongoing

Research institution and networks

Institutions

UPCET
First published: 01/02/2024
Last updated: 01/02/2024

Pharmacologie En Population cohorteS biobanqueS (PEPSS), Hopitaux de Toulouse
France
First published: 31/03/2022
Last updated: 05/04/2022
Study timelines

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

Data collection
Planned: 01/06/2015
Actual: 01/11/2015

Start date of data analysis
Actual: 10/01/2016

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

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

Sources of funding

- Other

More details on funding

Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM)

Regulatory

Was the study required by a regulatory body?
No
Methodological aspects

Study type

Study type list

**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 drug 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**
100000097335
Selective serotonin (5HT1) agonists
100000097325
Ergot alkaloids

Population studied

**Age groups**
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Estimated number of subjects
150000

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- Death all cause- Death related to cardiovascular event

Data analysis plan
Hazard ratio for cardiovascular events using a Cox proportional hazard model with covariates. Patients are followed-up for 90 days after their inclusion in the cohort, and HR estimates are 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 are CMUC, diabetes mellitus, COPD, dyslipidemia, hypertension, history of cardiovascular disease. Same approach will be performed for death events (all causes death and cardiovascular related death). Nested case-control study will allow to study the association between an abuse of triptans and the onset of cardiovascular events. A logistic regression will be performed to compare the risk of cardiovascular events, death all cause and cardiovascular death between patients unexposed to triptans and patients overusing triptans.

Documents

Study publications
Palmaro A, Braunstein D, Lanteri-Minet M, Baricault B, Boucherie Q, Pauly V, Do…
Palmaro A, Braunstein D, Lanteri-Minet M, Baricault B, Boucherie Q, Pauly V, Do…

Data management

ENCePP Seal
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
Data sources

Data source(s), other
SNIIRAM France, PMSI France

Data sources (types)
Administrative data (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