# 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

**PURI**
https://redirect.ema.europa.eu/resource/27270

**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 institution 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
Hospital/Clinic/Other health care facility
Educational Institution
ENCePP partner

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

France
**First published:** 31/03/2022
Last updated
01/07/2024

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

# Contact details

**Study institution contact**
Joëlle Micallef

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
(N02CC) 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.

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**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…

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# 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**

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