Association of Use of Angiotensin-converting Enzyme Inhibitors and Angiotensin II Receptor Blockers with fall and trauma-related hospitalization among elderly patients: a nationwide population-based cohort study

First published: 04/05/2022

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Study Ongoing

Administrative details

EU PAS number

EUPAS47042

Study ID

47043

DARWIN EU® study

No

Study countries

France

Study description

ARBs and ACE inhibitors are the most commonly prescribed antihypertensive drugs among adults in the world. They are first-line drugs for hypertension, heart failure and myocardial infarction. While large clinical trials and meta-analysis post marketing authorization showed no association between antihypertensive and fall, several observational studies on large cohorts of real-life patients have shown the opposite. Although these studies have assessed the risk of fall and trauma associated with RAS as a class, whether differences exist between ARBs and ACE inhibitors is unclear. Indeed, ARBs and ACE inhibitors have different pharmacodynamic mechanisms, which may in turn induce different antihypertensive effects. The primary mechanism of action of ARBs is to reduce AT1 receptor activation, even more effectively than ACE inhibitors. ARBs also promote higher activation of AT2 receptors, which enhances their antihypertensive action. Determine whether use of ARBs, when compared with ACE inhibitors, is associated with an increased risk of fall and trauma-related hospitalization among of 65 years and older a multivariable Cox proportional-hazards outcome models using

Study status

Ongoing

Research institutions and networks

Institutions

University Hospital Purpan

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Institution

Pharmacologie En Population cohorteS et biobanqueS

Contact details

Study institution contact

Julia GUION-FIRMIN julia_gf@yahoo.fr

Study contact

julia_gf@yahoo.fr

Primary lead investigator

François MONTASTRUC

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/01/2022

Actual: 31/01/2022

Study start date
Planned: 14/02/2022

Actual: 28/02/2022

Data analysis start date
Planned: 04/04/2022

Actual: 18/04/2022

Date of final study report
Planned: 01/07/2022

Sources of funding

- EU institutional research programme

More details on funding

CHU Martinique

Study protocol

Protocole ARA2 Chute.pdf (826.38 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Determine whether use of ARBs, when compared with ACE inhibitors, is associated with an increased risk of fall and trauma-related hospitalization among of 65 years and older

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C09A) ACE INHIBITORS, PLAIN

ACE INHIBITORS, PLAIN

(C09C) ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN

ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN

Population studied

Age groups

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

Estimated number of subjects

18097

Study design details

Outcomes

Occurrence of a hospitalization for fall or trauma during the follow-up. - Hospitalization for syncope or malaise during the follow-up. - Hospitalization for orthostatic hypotension during the follow-up. - Onset of death during the follow-up. - Onset of ICU hospitalization during the follow-up.

Data analysis plan

Primary analysis Descriptive analysis / Potential confounders / Incidence rates HRs with 95% CIs of fall and trauma with Cox proportional hazards with PS matching models Secondary analysis Repetition of the primary analysis for the risk of other serious events Sensitivity analysis Subgroup analyses / by varying the outcome / duration of use of drugs

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

Other

Data sources (types), other

Prospective patient-based data collection

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