Adherence to the major classes of anthypertensive theraphy (AMCA)

First published: 20/12/2022

Last updated: 28/01/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS50008

Study ID

50272

DARWIN EU® study

No

Study countries

☐ Sweden

Study description

Using the trial emulation method, an observational database of all Swedish residents ≥ 40 years of age starting antihypertensive therapy for the first time in a single pill between 2011 and 2018 will be analyzed. By cross referencing 4

national all-covering registers we will create an observational database of people initiating antihypertensive therapy in a setting of universal healthcare with negligible co-payment. The target trial emulation method will be used to create an observational study with minimal bias. Persistence on class and therapy level will be determined by following consequently retrieved prescriptions and calculating proportion of days covered. A multi-state framework will then be used were the patients are allowed to go back and forth between on (periods ≥ 80 % of treatment days covered) and off periods (periods <80 % of treatment days covered), with the addition of the absorbing states; death or cardiovascular event.

Study status

Ongoing

Research institutions and networks

Institutions

Uppsala University

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Karl Laurell karl.laurell@medsci.uu.se

Study contact

karl.laurell@medsci.uu.se

Primary lead investigator

Karl Laurell

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/02/2022

Actual: 01/02/2022

Study start date

Planned: 26/06/2020

Actual: 26/06/2020

Data analysis start date

Planned: 28/01/2022

Actual: 10/01/2024

Date of final study report

Planned: 28/04/2023

Sources of funding

- Other

More details on funding

Primary Care and Health, Region Uppsala, Sweden

Study protocol

Original studyprotocol.pdf(782.55 KB)

Study protocol updated.pdf(714.08 KB)

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:

Human medicinal product

Study topic, other:

Persistence

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To explore if persistence is associated to initial drug class of antihypertensive, when treating uncomplicated hypertension.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prescription event monitoring

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C03AA) Thiazides, plain

Thiazides, plain

(C03BA) Sulfonamides, plain

Sulfonamides, plain

(C08CA) Dihydropyridine derivatives

Dihydropyridine derivatives

(C09A) ACE INHIBITORS, PLAIN

ACE INHIBITORS, PLAIN

(C09BA) ACE inhibitors and diuretics

ACE inhibitors and diuretics

(C09BB) ACE inhibitors and calcium channel blockers

ACE inhibitors and calcium channel blockers

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

ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN

(C09DA) Angiotensin II receptor blockers (ARBs) and diuretics

Angiotensin II receptor blockers (ARBs) and diuretics

(C09DB) Angiotensin II receptor blockers (ARBs) and calcium channel blockers

Angiotensin II receptor blockers (ARBs) and calcium channel blockers

---

Medical condition to be studied

Essential hypertension

Population studied

Short description of the study population

People ≥ 40 years old with uncomplicated hypertension in Sweden

---

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

600000

Study design details

Outcomes

Persistence to different classes of antihypertensives.

Data analysis plan

The classes of antihypertensive medication will be compared using a Poisson regression model. The cohort in this study is recruited over a number of years, individuals are of different ages at baseline and the time from the first prescription may be of interest. Poisson models allow for multiple timescales to enter the model simultaneously and the connection between the Cox model and Poisson regression using time-split data is well known. Poisson models also allow treatment-timescale interaction, also known as non-proportional hazards, to be studied using interaction terms. Follow-up time within each individual will be split into intervals of 3 months in which the outcome rate is assumed to be constant. A change of state also splits follow-up time at the time of the event. All timescales will be modeled using cubic splines with five knots

Data management

Data sources

Data source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

National cause of death register Sweden, Longitudinal integrated database for health insurance and labour market studies (LISA) Sweden, National patient register Sweden

Data sources (types)

Disease registry

Drug dispensing/prescription data

Other

Data sources (types), other

Prescription event monitoring

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