Effectiveness of Indapamide SR on top of Perindopril on blood pressure change: a methodological study to validate effect of anti-hypertensive drugs in CPRD Aurum.

First published: 22/12/2021

Last updated: 23/04/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/44584

EU PAS number

EUPAS44583

Study ID

44584

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Antihypertensive treatments efficacy is demonstrated in Randomized Controlled Trials (RCT) based on frequent, iterative BP measures while these measurements are sparse in real life setting. The aim of this study is to assess whether this efficacy can be objectivised using Blood Pressure (BP) records collected in routine practice. In a main approach, this study will emulate, using Clinical Research Practice Datalink, a theoretical phase III RCT comparing the BP changes when adding indapamide SR on top of perindopril 4/5mg versus staying on perindopril 4/5mg alone, in patients who have uncontrolled hypertension.

Study status

Ongoing

Research institutions and networks

Institutions

Institut de Recherches Internationales Servier

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Institut de Recherches Internationales Servier Institut de Recherches Internationales Servier

Study contact

RWE.Dept@servier.com

Primary lead investigator

Nadjat Mounedji

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2020

Actual: 01/09/2020

Study start date

Planned: 14/06/2021

Actual: 14/06/2021

Data analysis start date

Planned: 15/06/2021

Actual: 15/06/2021

Date of final study report

Planned: 29/04/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Institut de Recherches Internationales Servier

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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

The overall aim of this study is to assess whether and how efficacy of antihypertensive therapy can be objectivised using Blood Pressure records

collected during routine clinical practice. In a main approach, the study will emulate a theoretical phase III study with the same antihypertensive treatments using the Clinical Research Practice Datalink (CPRD).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

PERINDOPRIL TERT-BUTYLAMINE

PERINDOPRIL ARGININE

INDAPAMIDE

Medical condition to be studied

Essential hypertension

Population studied

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

13988

Study design details

Outcomes

Primary outcome will be SBP change between SBP at ID and the closest SBP value to week 8 in a window of 4 weeks to 24 weeks after ID. Change in DBP between DBP at ID and the closest DBP value to week 8 in a window of 4 weeks to 24 weeks after ID. SBP change between SBP at ID and the mean of all the SBP values recorded in a window of 4 weeks to 24 weeks after ID, instead of the closest record to week 8. Percentage of patients who reach BP control at week 8.

Data analysis plan

Patients in both groups will be matched using a propensity score. The primary outcome that will be SBP change between baseline and week 8, will be assessed using a linear regression model. Missing data will be handled using multiple imputation and return-to-baseline approaches according to missing pattern. The secondary objective will further assess how BP effect of antihypertensive drugs can be measured considering real life context (less selected population, sparse BP measures). Thus, different methods like alternative definitions of population, alternative definitions of outcomes (e.g. BP control), and complementary statistical approaches (Standardized Mortality Ratio and Inverse probability censoring weighting) will be used

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Data sources (types)

Electronic healthcare records (EHR)

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