Bendroflumethiazide versus Indapamide for Primary Hypertension: Observational (BISON) study within CPRD

First published: 13/09/2018
Last updated: 17/05/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/34126

EU PAS number
EUPAS25523

Study ID
34126

DARWIN EU® study
No

Study countries
United Kingdom

Study description
This study aims to compare the effects of prescribing indapamide, a thiazide-like diuretic, with bendroflumethiazide, a thiazide diuretic, as the first-line choice of diuretic in the treatment of hypertension. The outcome measure will be a composite of non-fatal myocardial infarction, acute coronary syndrome, stroke, acute decompensated heart failure or death from cardiovascular causes. We will identify in CPRD all patients aged 18 years and over with first diagnosis of hypertension after 1987. Among them, we will form two groups with first ever prescription of indapamide or bendroflumethiazide. We will follow the groups either to the date of last prescription, date of medication switch, date of additional

medication for hypertension (such as beta-blockers, calcium channel blockers, ACE inhibitors, alpha-blockers, ARBs or other antihypertensive medication), date of outcome, date of de-registration with the medical practice or the date of last practice data collection. We will also extract information on patient age, sex, medical practice, co-morbidities, co-prescribed medication, smoking, weight and alcohol consumption. Incidence of event rates will be calculated in each group. Descriptive analysis, and univariate and multivariate Cox regression survival models will be used as appropriate. Subgroup analyses will be implemented for known risk factors. This large population-based study may provide new evidence on the potential benefit of treating hypertensive patients with indapamide or bendroflumethiazide and may inform future clinical trials.

Study status
Ongoing

Research institution and networks

Institutions

University of Dundee
United Kingdom
First published: 01/02/2024
Last updated
01/02/2024
Institution
Educational Institution

Contact details

Study institution contact
Thomas MacDonald
Study contact

t.m.macdonald@dundee.ac.uk
Primary lead investigator
Thomas MacDonald
Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
01/01/2018

Study start date
Actual:
13/09/2018

Date of final study report
Planned:
30/06/2020

Sources of funding

- Other

More details on funding

FARR Institute research grant and, MEMO departmental funds

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Other study registration identification numbers and links

ISAC protocol 17_232https://www.cprd.com/isac/

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Scope of the study:
Disease epidemiology
Drug utilisation
Effectiveness study (incl. comparative)

Main study objective:
To compare, in an observational study using CPRD data, the effect of bendroflumethiazide versus indapamide on of risk of myocardial infarction (MI), acute coronary syndrome, stroke, acute decompensated heart failure & death from cardiovascular causes, in patients with hypertension.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
100000094784
bendroflumethiazide
100000094819
indapamide

Medical condition to be studied
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
200000

Study design details

Outcomes
The first occurrence of any event within the composite outcome of myocardial infarction (MI), acute coronary syndrome not resulting in myocardial infarction, stroke, acute decompensated heart failure, death from cardiovascular causes. The individual components of the primary composite outcome described above, death from any cause, primary outcome or death from any cause.

Data analysis plan
We will analyse time trends in the incidence of hypertension between 1987 and 2015 by sex, age and year of diagnosis. We will describe the antihypertensive therapies prescribed following the diagnosis of hypertension. We will assume that patients were treated with either bendroflumethiazide or indapamide if they received at least two prescriptions for that medication following the diagnosis of hypertension. We will construct two groups by matching patients on a propensity score, namely the probability of exposure to either indapamide or bendroflumethiazide, estimated from a logistic regression model. Time from the Index date to the outcome will be analysed using Cox proportional hazards model. We will conduct two types of analysis: per protocol primary analysis (considering patients only when they were exposed) and intention to treat sensitivity analysis (follow up until outcome or last follow up irrespective whether treatment was discontinued, switched or intensified).

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