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

**First published:** 13/09/2018

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Study Ongoing

## Administrative details

**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.

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**Study status**

Ongoing

# Research institutions and networks

## Institutions

## University of Dundee

United Kingdom

**First published:** 01/02/2024

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Institution | Educational Institution

# Contact details

### Study institution contact

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Study contact

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### 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

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**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

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**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**

(C03AA01) bendroflumethiazide

bendroflumethiazide

(C03BA11) indapamide

indapamide

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**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)

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**Estimated number of subjects**

200.000

## 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.

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**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

## 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 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