Comparison of the medication adherence of patients treated with telmisartan/hydrochlorothiazide or telmisartan/amlodipine FDC versus double-pill combination therapy in real-world Japanese therapeutic practice

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Study Ongoing

Administrative details

EU PAS number

EUPAS19696

Study ID

29656

DARWIN EU® study

No

Study countries

Japan

Study description

This is a retrospective, observational study in Japanese patients with hypertension based on Japanese prescription database. The primary objective of this study is to compare the medication adherence measured by PDC of patients with FDC or double-pill combination therapy in real-world Japanese therapeutic practice. The further objective of this study is how much influence the background of patients to the adherence.

Study status

Ongoing

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Primary lead investigator

Seiichiro Nishimura

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/06/2017

Actual: 30/06/2017

Study start date

Planned: 18/01/2018

Actual: 11/01/2018

Date of final study report

Planned: 29/03/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.

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:

Drug utilisation

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The primary objective of this study is to compare the medication adherence measured by PDC (Proportion of Days Covered) of patients with FDC (fixed dose combination) or double-pill combination therapy in real-world Japanese therapeutic practice.

Study drug and medical condition

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

TELMISARTAN

AMLODIPINE

HYDROCHLOROTHIAZIDE

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

3275

Study design details

Outcomes

PDC of patients treated with single- and double- combination therapy, Demographic and clinical characteristics of patients treated with single- and double- combination therapy

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Data analysis plan

Caliculate and compare the medication adherence (PDC) of patients with FDC or double-pill combination therapy in the following groups:1) • Telmisartan+ hydrochlorothiazide double-pill combination • Telmisartan/hydrochlorothiazide single-pill combination (Micombi®) 2) • Telmisartan+amlodipine double-pill combination • Telmisartan/amlodipine single-pill combination (Micamlo®) Data are shown as the mean ±SD. Variables were compared by using Student's t-test, or $\chi 2$ test, as appropriate. A p value less than 0.05 was accepted as indicative of statistical significance.To compare adjusted differences among single- and double-pill cohorts with respect to medication adherence (PDC≧80%), logistic regression model was applied.

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)

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