The special drug use-results survey on long-term use of telmisartan 80 mg/amlodipine 5 mg/hydrochlorothiazide 12.5 mg fixed dose combination tablets in Patients with Hypertension in Japan (Japanese Micatrio PMS, long term)

First published: 11/01/2017

Last updated: 26/02/2020

Study Finalised

Administrative details

EU PAS number

EUPAS17181

Study ID

33818

DARWIN EU® study

No

Study countries

Japan

Study description

To evaluate real-world safety, effectiveness and appropriate use of Micatrio® Combination Tablets treatment in patients with hypertension

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Multiple centres: 100 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Rie Ikeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/09/2016

Actual: 13/04/2016

Study start date

Planned: 20/01/2017

Actual: 07/02/2017

Data analysis start date

Planned: 20/01/2017

Actual: 07/02/2017

Date of final study report

Planned: 31/03/2020

Actual: 20/02/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.,

Study protocol

1348.6_protocol_Synopsis.pdf(98.23 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Study to evaluate real-world safety, effectiveness and appropriate use of Micatrio® Combination Tablets treatment in patients with hypertension

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Non-interventional, prospective, observational, single arm

Study drug and medical condition

Medical condition to be studied

Hypertension

Population studied

Short description of the study population

Patients who diagnosed with hypertension based upon the most recent JSH guideline.

Inclusion criteria

- Patients who are prescribed with Micatrio® Combination Tablets by the discretion of investigators based on the Japanese package insert
- Patients who have never been treated with Micatrio® Combination Tablets before enrolment

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Age groups

Adolescents (12 to < 18 years)

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)

Special population of interest

Renal impaired

Estimated number of subjects

500

Study design details

Outcomes

The frequency of patients with any suspected adverse drug reactions (ADRs), change from baseline in blood pressure at Week 52.

Data analysis plan

Descriptive statistics will be summarized for safety and efficacy. Incidence of adverse drug reactions.Change from baseline in blood pressure at Week 52.Subgroup analyses.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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