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

First published: 29/06/2017 Last updated: 30/01/2025





### Administrative details

#### **EU PAS number**

**EUPAS19696** 

Study ID

29656

**DARWIN EU® study** 

No

**Study countries** 

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#### **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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Study contact

seiichiro.nishimura@boehringer-ingelheim.com

### **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

#### **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  $\pm$ 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 $\geq$ 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

# Data quality specifications

#### **Check conformance**

Unknown

### **Check completeness**

Unknown

### **Check stability**

Unknown

### **Check logical consistency**

Unknown

### Data characterisation

#### **Data characterisation conducted**

No