

# 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:** 17/12/2025

Study

Cancelled

## Administrative details

### EU PAS number

EUPAS19696

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### Study ID

29656

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### DARWIN EU® study

No

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### Study countries

☐ Japan

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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.

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### Study status

Cancelled

## Research institutions and networks

### Institutions

**Boehringer Ingelheim**

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

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**Institution**

## Contact details

### Study institution contact

Seiichiro Nishimura seiichiro.nishimura@boehringer-  
ingelheim.com

Study contact

[seiichiro.nishimura@boehringer-ingelheim.com](mailto: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

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**Study start date**

Planned: 18/01/2018

Actual: 11/01/2018

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**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

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

Not applicable

## Methodological aspects

Study type

Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Study design:**

retrospective, observational study

**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

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### **Anatomical Therapeutic Chemical (ATC) code**

(C09CA07) telmisartan

telmisartan

(C08CA01) amlodipine

amlodipine

(C03AA03) hydrochlorothiazide

hydrochlorothiazide

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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**

3275

## **Study design details**

### **Setting**

Japanese prescription database

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### **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**

Calculate 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)

[Drug prescriptions](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No