

# Adherence to antihypertensive therapy: analysis of initiation, implementation, discontinuation and possible risk factors in Portuguese primary care units

**First published:** 16/12/2014

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/16947>

### EU PAS number

EUPAS7757

### Study ID

16947

### DARWIN EU® study

No

### Study countries

Portugal

### Study description

Non-adherence to antihypertensive therapy is an important component of preventable cardiovascular morbidity and mortality, mostly relevant in the case of a recent diagnosis or prescription of new antihypertensive drugs. It has been estimated that up to 30% of patients fail to initiate prescribed therapy and that during the first year of treatment up to 50% of patients discontinue their therapy. The main objective of the study is to determine adherence to antihypertensive therapy in newly treated hypertensive patients in primary care units from Region of Lisbon and Tagus Valley. The secondary objective is to identify

risk factors for non-adherence. We will conduct an observational retrospective cohort study. The study population is formed by all newly diagnosed and treated hypertensive patients in the primary care units of Region of Lisbon and Tagus Valley during the first trimester of 2011. Prescription and claims data will be collected from SIARS for each patient during a follow-up of 2 years after index date and a run-in period of 6 months. Initiation is determined by picking-up the first prescription in a pharmacy within a 180-day period. Implementation of therapy is measured with Medication Possession Ratio and persistence, as a measure of the duration of time from initiation to discontinuation is determined by refill persistence according to a maximum allowed treatment gap of 90 days. This allows us to separate the population in two cohorts: adherents and non-adherents. Differences between the two groups will be handled by logistic regression. Little is known in Portugal about adherence to antihypertensive therapy, especially at a population level. To our best knowledge this will be the first study in the country to measure medication adherence with prescription and claims data. Data emerging from this study will hopefully allow a framework to identify patients at risk for non-adherence in its different manifestations and develop strategies to reduce that risk.

### Study status

Finalised

## Research institution and networks

### Institutions

Chronic Diseases Research Center of the Faculdade de Ciências Médicas da Universidade Nova de Lisboa (CEDOC/FCM-UNL)

Portugal

**First published:** 28/10/2013

Last updated

27/03/2024

Institution

ENCePP partner

Educational Institution

## Contact details

### Study institution contact

Andre Coelho

Study contact

[andre.coelho@estesl.ipl.pt](mailto:andre.coelho@estesl.ipl.pt)

**Primary lead investigator**

**Pedro Caetano**

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned:

01/09/2014

Actual:

01/09/2014

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### **Study start date**

Planned:

15/12/2014

Actual:

15/12/2014

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### **Data analysis start date**

Planned:

01/01/2015

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### **Date of final study report**

Planned:

30/09/2015

Actual:

31/07/2016

## Sources of funding

- Other

## More details on funding

University

## Study protocol

[Protocolo\\_ENCePP.pdf](#)(360.95 KB)

## 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:**

Disease /health condition  
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 data collection

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**Main study objective:**

The main objective of the study is to determine adherence to antihypertensive therapy in newly treated hypertensive patients in primary care units from Region of Lisbon and Tagus Valley.

### Study Design

**Non-interventional study design**

Cohort

### Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

100000094780

COMBINATIONS OF ANTIHYPERTENSIVES IN ATC-GR. C02

100000094781

DIURETICS

100000094984

BETA BLOCKING AGENTS

100000095062

CALCIUM CHANNEL BLOCKERS

100000095100

AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

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**Medical condition to be studied**

Hypertension

## Population studied

**Short description of the study population**

Newly diagnosed and treated hypertensive patients in the primary care units of Region of Lisbon and Tagus Valley during the first trimester of 2011.

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**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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**Special population of interest**

Other

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**Special population of interest, other**

Hypertensive patients

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**Estimated number of subjects**

10204

## Study design details

**Outcomes**

Patterns in initiation, implementation and discontinuation of antihypertensive therapy. The secondary objective is to identify risk factors for non-adherence.

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## Data analysis plan

Initiation will be quantified as the proportion of patients not exceeding a 180-day period after index prescription. Will be analyzed using standard survival analysis. Implementation will be quantified by estimation of MPR, expressed as the number of days' supply obtained during observation period/number of days in the observation period. For patients receiving multiple drugs, MPR will be calculated for each drug separately, and the overall MPR will be the mean of the individual values. A threshold of 80% will be used to dichotomize between good and poor implementation. Logistic regression will be used to estimate relative risk with 95% CI for poor implementation. Persistence will be quantified as the proportion of patients not exceeding the maximum allowed treatment gap during follow-up. Kaplan-Meier analysis will be used to calculate persistence and 95% CI after 1 and 2 years. Cox proportional hazard regression will be used to estimate hazard ratios of predictors for discontinuation.

## Documents

### Study results

[10.pdf](#)(716.13 KB)

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## Data management

## ENCePP Seal

**This study has been awarded the ENCePP seal**



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**Conflicts of interest of investigators**

[Annex5\\_DolForm\\_AndreCoelho.pdf.PDF](#)(136.02 KB)

[Annex5\\_DolForm\\_PedroCaetano.pdf.PDF](#)(148.58 KB)

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**Composition of steering group and observers**

[CompositionSteeringGroupObservers.pdf](#)(52.46 KB)

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**Signed code of conduct**

[2014-0028-CoC Declaration-SDPP\\_7757.pdf](#)(1.12 MB)

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**Signed code of conduct checklist**

[2014-0028-CoC Checklist-SDPP\\_7757.pdf](#)(546.02 KB)

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**Signed checklist for study protocols**

[2014-0028-Checklist-Protocols-SDPP\\_7757.pdf](#)(167.11 KB)

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## Data sources

**Data source(s), other**

SIARS Portugal

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**Data sources (types)**

[Administrative data \(e.g. claims\)](#)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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**Data sources (types), other**

Prescription event monitoring

## 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