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

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 is its different manifestations and develop strategies to reduce that risk.

Study status

Finalised

Research institutions 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 | Educational Institution | ENCePP partner

Contact details

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Study contact

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Primary lead investigator

Pedro Caetano

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2014

Actual: 01/09/2014

Study start date
Planned: 15/12/2014

Actual: 15/12/2014

Data analysis start date
Planned: 01/01/2015

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

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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

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

(C02N) COMBINATIONS OF ANTIHYPERTENSIVES IN ATC-GR. C02

COMBINATIONS OF ANTIHYPERTENSIVES IN ATC-GR. C02

(C03) DIURETICS

DIURETICS

(C07A) BETA BLOCKING AGENTS

BETA BLOCKING AGENTS

(C08) CALCIUM CHANNEL BLOCKERS

CALCIUM CHANNEL BLOCKERS

(C09) AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

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.

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)

Special population of interest

Other

Special population of interest, other

Hypertensive patients

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.

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' suplly 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)

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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

Annex5_DoIForm_AndreCoelho.pdf.PDF (136.02 KB)

Annex5_DoIForm_PedroCaetano.pdf.PDF (148.58 KB)

Composition of steering group and observers

CompositionSteeringGroupObservers.pdf (52.46 KB)

Signed code of conduct

2014-0028-CoC Declaration-SDPP_7757.pdf (1.12 MB)

Signed code of conduct checklist

2014-0028-CoC Checklist-SDPP_7757.pdf (546.02 KB)

Signed checklist for study protocols

2014-0028-Checklist-Protocols-SDPP_7757.pdf (167.11 KB)

Data sources

Data source(s), other

SIARS Portugal

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prescription event monitoring

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