

Intensive Monitoring in Portugal: a Model to Assess Medicines in Real-Life Conditions. Antidiabetics as example. (MOMI)

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Study

Ongoing

Administrative details

EU PAS number

EUPAS8433

Study ID

8434

DARWIN EU® study

No

Study countries

 Portugal

Study description

Aiming to fill the gap between clinical trials, database studies and spontaneous reporting data, an intensive monitoring model - that can monitor selected drugs over time - is proposed to be implemented in Portugal. By pharmacy based tracking of patients and drug usage in a life-cycle based fashion, this model is actively focused on gathering post-authorization data, mainly safety, since the first day of drug use. In what concerns to methods, a database comprising 3 different sources: 1) baseline subject-reported demographics and health characteristics to be administered by the community pharmacy, 2) telephone follow-up questionnaires on subject-reported risk (adverse events), (proxy of)benefit (e.g. EQ5D) and pattern of use data to be administered by the research team of the project (pharmacists) and, 3) pharmacy records was developed. All treatment naïve patients initiating treatment (inception cohort) with DPP-4, GLP-1 and SGLT2 visiting one of the participant pharmacies will be invited and to give consent to participate in the study. This is an academic project (Carla Torre's PhD project) from the Faculty of Pharmacy of the University of Lisbon under the supervision of Prof. dr. Ana Paula Martins (Faculty of Pharmacy of the University of Lisbon) and of Prof. dr. Hubert G. Leufkens (Utrecht Institute for Pharmaceutical Sciences, Division of Pharmacoepidemiology and Clinical Pharmacology, Faculty of Science, Utrecht University). This study is being conducted at the Centre for Health and Research (CEFAR), an ENCePP centre - that belongs to the Portuguese National Association of Pharmacies. According to the Portuguese legislation (Law no. 67/98, 26th October), this study was submitted and approved by the Portuguese Data Protection Authority (CNPD). The study was approved by the ethics committee of the Institute of Public Health of the University of Porto.


Study status

Ongoing

Research institutions and networks

Institutions

National Association of Pharmacies Portugal (ANF)

 Portugal

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Institution

Pharmaceutical association/federation

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Carla TORRE

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/01/2012

Study start date

Planned: 10/11/2014

Actual: 10/11/2014

Data analysis start date

Planned: 15/04/2015

Date of interim report, if expected

Planned: 01/06/2015

Date of final study report

Planned: 31/12/2016

Sources of funding

- Other

More details on funding

CEFAR (CEFAR (Centre for Health Research & Evaluation) - National association of Pharmacies

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

If 'other', further details on the scope of the study

Active Surveillance (Intensive Monitoring)

Main study objective:

By pharmacy based tracking of patients and drug usage in a life-cycle based fashion, this model is actively focused on gathering post-authorization data, mainly safety, since the first day of drug use.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

intensive monitoring schemes

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

SITAGLIPTIN

VILDAGLIPTIN

SAXAGLIPTIN
LINAGLIPTIN
LIRAGLUTIDE
EXENATIDE
DAPAGLIFLOZIN

Medical condition to be studied

Type 2 diabetes mellitus

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

1200

Study design details

Outcomes

- Adverse drug events (ADE) self-reported by patients - (real-world) drug utilization pattern, - Self reported hypoglycemia- Health-related quality of life (EQ-5D)- RCT external validity (Portuguese population)

Data analysis plan

The nr of patients reporting an ADE, the proportion of serious ADE defined according to the CIOMS criteria, and the incidence densities for all ADE during treatment will be calculated. The ADE will be divided into labelled or not labelled according to the European Public Assessment Report (EPAR) of the monitored drug. Generalized Linear Models will be conducted to explore and to identify factors associated with the ADE. Longitudinal models will be used to explore the association of each covariate with time to ADE (time-to-event analysis). Through the patient therapeutic profile, the existence of drug-drug interactions will be identified as well as the eventual existence of drug-disease interactions associated with the monitored drug. The reported monitored drug pattern of use will be described and compared with the one defined in the EPAR. The statistical significance level adopted will be 5% and statistical analysis will be done using the SAS Enterprise Guide v4.1.

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.

Conflicts of interest of investigators

[Declaração de Honra.pdf](#) (132.63 KB)

Data sources

Data sources (types)

Drug dispensing/prescription data

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