Observational, Cross-sectional Multicenter Study to Characterize and to Determine the Proportion of Ambulatory Type 2 Diabetes Mellitus Patients with Mild to Moderate Hypoglycemia Episodes according to their background therapy in Portugal; HypoglycemIa in POrtugal Study – PHARMAcy (HIPOS-PHARMA)

First published: 17/03/2016

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/13487

EU PAS number

EUPAS12848

Study ID

13487

DARWIN EU® study

No

Study countries

☐ Portugal

Study description

Diabetes Mellitus (DM) is a chronic illness with both incidence and prevalence increasing worldwide. Although life style modifications play an important role in type 2 DM treatment, due to the progressive natural course of the disease, most of the patients also require pharmacotherapy targeted to glycemic control. One of the major challenges in the treatment of DM is to achieve glycemic control while avoiding episodes of hypoglycemia. In Portugal, hypoglycemia severity and frequency remain poorly documented. In light with this, the aim of this study is to characterize and to determine the proportion of ambulatory type 2 DM patients with mild to moderate hypoglycemia episodes in Portugal treated with antihyperglycemic agent (AHA).This is an observational, cross-sectional multicenter study of treated type 2 DM, recruited through community pharmacies, which will collect information through a structured questionnaire delivered upon the presentation of a prescription to purchase an AHA. Study population comprised type 2 diabetics aged over 40, which agree to participate and sign an informed consent. Patients are required to be at least for 3 months in the current AHA and will be assigned into one of the four different therapeutic groups (Group 1: Insulin based therapy, Group 2: Secretagogue based therapy, Group 3: Other AHA excluding Secretagogue and insulin, and Group 4: Combination of Insulin and Secretagogue). This study was approved by the Bioethics Institute of the Catholic University of Portugal.

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: 04/01/2016

Actual: 04/01/2016

Study start date
Planned: 04/04/2016

Actual: 04/04/2016

Data analysis start date
Planned: 31/05/2016

Date of final study report
Planned: 31/08/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme (MSD), Medinfar Group and Tecnifar

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

Main study objective:

Primary objectives:To characterize and to determine the proportion of ambulatory Type 2 Diabetes Mellitus patients with mild to moderate hypoglycemia episodes in Portugal treated with AHA.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

1740

Study design details

Outcomes

Primary outcomes: Proportion of mild to moderate hypoglycemic episodes in ambulatory patients treated with AHA. Secondary outcomes: 1) Socio-demographic (gender, age, educational level, employment status, marital status, co-residence status) and self-reported clinical information (including, BMI, co-morbidities, concomitant medication, duration of disease), 2) Healthcare resources consumption and patient days of work/school lost associated with mild to moderate hypoglycemic' episodes.

Data analysis plan

Discrete variables will be summarized by absolute and relative counts. Percentages will be calculated using the number of participants for whom data will be available and missing values will be stated. Continuous variables will be summarized using central tendency (mean, median) and dispersion measures (standard deviation and inter-quartile range).The comparison between participants and refusals regarding basic socio-demographic characteristics (age group, gender, specialty and location of the prescribing physician) will be performed through the Chi-Square test or Fisher Exact test (if applicable).Descriptive statistics will adopt a 95% confidence interval. Logistic Regression will be used to explore factors that potentially may contribute to mild to moderate hypoglycemic episodes. Odds Ratio will be calculated for each significant association, using 95% confidence intervals.

Documents

Study publications

Bramlage P, Gitt AK, Binz C, Krekler M, Deeg E, Tschöpe D. Oral antidiabetic tr…

Walz L, Pettersson B, Rosenqvist U, Deleskog A, Journath G, Wändell P. Impact o…

Inzucchi SE, Bergenstal RM, Buse JB, Diamant M, Ferrannini E, Nauck M, Peters A…

Childs BP, Clark NG, Cox DJ, Cryer PE. Defining and reporting hypoglycemia in d…

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Structured questionnaire

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