Pattern of use of incretin-based drugs in clinical practice

First published: 13/11/2015

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10902

Study ID

28087

DARWIN EU® study

No

Study countries

☐ Italy

Study description

Incretin based drugs represent a class of hypoglicemic agents including different molecules approved during the last decade for the treatment of type 2 diabetes (T2DM). The clinical efficacy of this class of drugs in the treatment of

T2DM relies on the potentiaton of the activity of the glucagon-like peptide 1 (GLP-1), an endogenous hormon belonging to the family of incretins that exerts an important role in the glycemic omeostasis. In particular, on the basis of the mechanism of action, incretin-based drugs can be distinguished in two groups: glucagon like peptide-1 analogues and dipeptidilpeptidase-4 inhibitors (DPP4i). Different randomized clinical trials demonstrated a positive risk/benefit profile for these hypoglicemic agents. However, given the relatively recent commercialization, evidence on the pattern of use of these medications in clinical practice is still scarce. Different incretin based medicines are currently available in Italy. Although a trend of increase of their use has been reported in literature, specific information concerning GLP-1 analogues and DPP-4i or the individual molecules belonging to the two groups are still lacking. Moreover, since the effectiveness and safety profile of these drugs cannot be considered completely established yet, evidence on the exposure of the general population to these medications, as well as the characterization of treated patients, becomes of paramount importance for planning large scale observational pharmacoepidemiological studies. Therefore, the aim of this study is to describe in greater details the pattern of use of incretin-based drugs in a large sample of the Italian general population. For this purpose, electronic health records from three population-based administrative data bases collecting information on almost 6 million inhabitants from 2 Italian regions, Tuscany and Umbria, and one Local Health Authority, Caserta, will be analyzed.

Study status

Finalised

Research institutions and networks

Institutions

Agenzia regionale di sanità della Toscana (ARS)

Italy

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Institution | EU Institution/Body/Agency | ENCePP partner

Department of Biomedical and Dental Sciences and Morphofunctional Imaging, University of Messina

Italy

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

National Centre for Epidemiology, Italian National Institute of Health Rome, Italy

Contact details

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Study contact

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Primary lead investigator

Roberto Giuseppe

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/09/2015

Study start date

Actual: 09/11/2015

Date of final study report

Planned: 31/01/2017

Actual: 31/01/2017

Sources of funding

- Other

More details on funding

This is an independent study based on a spontaneous initiative of the participanting partners

Study protocol

Pattern of use of incretin based drugs in clinical practice.pdf(52.3 KB)

Pattern of use of incretin based drugs in clinical practice_version_1.1.pdf(62.27 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:

To describe in greater details the pattern of use of incretin-based drugs in large sample of the Italian general population.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Pharmacoepidemiological study

Study drug and medical condition

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

SITAGLIPTIN

VILDAGLIPTIN

SAXAGLIPTIN

ALOGLIPTIN

LINAGLIPTIN

EXENATIDE

LIRAGLUTIDE

LIXISENATIDE

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

All subjects registered in the administrative databases of Tuscany, Umbria and Caserta between January 1, 2008 and December 31, 2014 who had ≥18 years of age and at least 365 days of look-back period.

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

6000000

Study design details

Data analysis plan

The annual incidence and prevalence of use of incretin-based therapies, in the general population will be calculated per each year of the period 2008-2014. The annual percentages of incident and prevalent incretin users on total number of users of antidiabetics will be observed. Annual percentage of new users of GLP-1 analogues, DPP-4 inhibitors and relevant actcive principles belonging to the two groups will be calculated on the total number of new users of incretin-based therapies. Incident incretin users will be described in terms of demographic characteristics, previous antidiabetics treatments and other drug therapies.

Documents

Study results

poster_incretin_Glasgow.pdf(461.18 KB)

Study publications

Roberto G, Barone-Adesi F, Giorgianni F, Pizzimenti V, Ferrajolo C, Tari M, Bar...

Data management

Data sources

Data source(s)

ARS Toscana

Data source(s), other

Regional Health Authority of Umbria Italy, Local Health Authority of Caserta Italy

Data sources (types)

Administrative healthcare records (e.g., claims)

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

Unknown