Time to treatment intensification in patients receiving metformin+incretin-based medicines versus metformin+other hypoglicemics (Time to treatment intensification with incretins)

First published: 01/08/2017

Last updated: 22/02/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/28096

EU PAS number

EUPAS20169

Study ID

28096

DARWIN EU® study

No

Study countries

Italy

Study description

Due to the progressive nature of tipe 2 diabetes, antidiabetic drugs tend to lose their efficacy over time so that treatment intensification is required. Current guidelines recommend metformin as the first choice in newly treated patients with type 2 diabetes. Among possible second-line add-on treatments, incretin-based medicines have been associated to a more durable glycemic control, although available evidence from observational studies is conflicting. The aim of this study is to the analyse routinely collected Italian admistrative data collected from different local and regional health authorities in order to compare the time to treatment intensification in patients with type 2 diabetes receiving incretin-based medicines versus other non-insulin antidiabetics as add-on therapy to metformin.

Study status

Planned

Research institutions and networks

Institutions

Agenzia regionale di sanità della Toscana (ARS)

Italy

First published: 01/02/2024

Last updated: 12/03/2024

Institution | EU Institution/Body/Agency | ENCePP partner

Pharmacoepidemiology Research Group, University of Eastern Piedmont (UPO)

Italy

First published: 07/11/2016

Last updated: 29/07/2024

Institution | Educational Institution | ENCePP partner

Pharmacoepidemiology Unit - National Centre for Epidemiology, Surveillance and Health Promotion, Istituto Superiore di Sanità (ISS)

Italy

First published: 23/03/2010

Last updated: 18/09/2023

Institution | Educational Institution | Laboratory/Research/Testing facility | ENCePP partner

Department of Pharmacology, University of Bologna (UNIBO)

Italy

First published: 25/06/2010

Last updated: 13/02/2012

Institution | Educational Institution | ENCePP partner

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

Italy

First published: 29/11/2021

Last updated: 20/08/2024

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

Contact details

Study institution contact

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Primary lead investigator

Roberto Giuseppe

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/01/2017

Study start date
Planned: 15/09/2017

Date of final study report
Planned: 31/08/2019

Sources of funding

- Other

More details on funding

This was a spontaneous initiative of the researchers participating to the project.

No fubndings were received from any external source.

Study protocol

Time to treatment intensification_incretins vs other hypoglicemics_Protocol_v1.1.pdf(298.9 KB)

Time to treatment intensification_incretins vs other hypoglicemics_Protocol_v1.2.pdf(311.15 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:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To compare the time to treatment intensification in patients with type 2 diabetes receiving incretin-based medicines versus other non-insulin antidiabetics as add-on therapy to metformin.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10BH) Dipeptidyl peptidase 4 (DPP-4) inhibitors

Dipeptidyl peptidase 4 (DPP-4) inhibitors

(A10BB) Sulfonylureas

Sulfonylureas

(A10BG) Thiazolidinediones

Thiazolidinediones

(A10) DRUGS USED IN DIABETES

DRUGS USED IN DIABETES

(A10BX02) repaglinide

repaglinide

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

20000

Study design details

Outcomes

Treatment intensification, i.e. insulin initiation or add-on of a third non-insulin antidiabetic, 1) insulin initiation 2) add-on of a third non-insulin antidiabetic drug3) switch to a third non-insulin antidiabetic drug

Data analysis plan

Survival curves describing the time to treatment intensification will be plotted with the Kaplan-Meier method. The log rank test will be used to test the statistical significance of the difference between different groups.Cox regression models will be applied to estimate hazard ratios, with 95% confidence intervals, and compare the time to treatment intensification from

index prescription in patients treated with MET+DPP4i versus those in the other exposure categories. Variables measured at baseline will be included in the model to account for their potential confounding effect.

Documents

Study publications

Time to Treatment Intensification in Patients Receiving DPP4 Inhibitors Versus ...

Data management

Data sources

Data source(s)

ARS Toscana

Data source(s), other

Regional Administrative databases of Umbria Italy, Regional Administrative databases of Piedimont Italy, Administrative database of the Local Helath Authority of Caserta Italy

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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