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



Administrative details

EU PAS number

EUPAS20169

Study ID

28096

DARWIN EU® study

No

Study countries

∏ltaly

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, incretinbased 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

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Institution

EU Institution/Body/Agency

ENCePP partner



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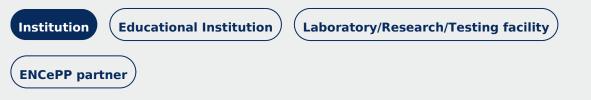


Pharmacoepidemiology Unit - National Centre for Epidemiology, Surveillance and Health Promotion, Istituto Superiore di Sanità (ISS)

ltaly

First published: 23/03/2010

Last updated: 18/09/2023



Department of Pharmacology, University of Bologna (UNIBO)

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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: 16/01/2017 **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

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

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.

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

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