Study about the results of the addition of a sulfonylurea, DPP4 inhibitors or SGLT2 inhibitors as a second antidiabetic drug in patients with diabetes mellitus type 2 in treatment with metformin and insufficient glycemic control. (eControl Met +)

First published: 05/05/2018

Last updated: 14/03/2024

Study Planned

Administrative details

EU PAS number

EUPAS23769

Study ID

23770

DARWIN EU® study

No

Study countries

Spain

Study description

Main objective:To compare the proportion of patients that achieve the reduction of HbA1c of at least 0.5%, and weight reduction of at least 3%, after the addition of a sulfonylurea, an DPP-4i or an SGLT-2i to the treatment with metformin in patients with T2DM and insufficient glycemic control up to a maximum of 24-month follow-up period.Methodology:Retrospective longitudinal cohort study with a maximum of 24-month follow-up period. Data will be collected from SIDIAP databases, which obtains data from electronic health care records of 75% of the Catalonia population attended in Primary Care facilities. We define as study population, patients diagnosed with type 2 diabetes mellitus on treatment with metformin and insufficient glycemic control that initiate treatment with a sulphonylurea, a DPP-4i or a SGLT-2i as a second antidiabetic drug during 2010-2015. The 3 cohorts will be formed and matched by propensity score technique according to age, sex, HbA1c and weight at the time of inclusion. Main determinations: Weight and Hb1Ac during 6, 12 and 24 months of follow-up and baseline characteristics for demographic variables and comorbidities related to their addition to the prescribed treatment. Statistical analysis: For the main analysis it will be used, the regression model of the mixed effects line and the COX models for the estimation of incidence and risk rates. Each dependent variable will be adjusted for baseline demographic factors and for predictive factors.Expected results:The data obtained from this study will improve the knowledge about the effects of the addition of a second oral antidiabetic.Relevance: There is a need for a large-scale observational study to know the effects of the three most common strategies for the second therapeutic choice for T2DM in real practice conditions.Keywords: Complications, glycemic control, type 2 diabetes mellitus, treatment.

Study status

Planned

Research institutions and networks

Institutions

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/05/2025

Institution | **Educational Institution** | **Laboratory/Research/Testing facility** | **Not-for-profit** | **ENCePP partner**

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Contact details

Study institution contact

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Study contact

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Primary lead investigator

Josep Franch-Nadal

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/05/2018

Study start date

Planned: 01/06/2018

Data analysis start date

Planned: 01/10/2018

Date of interim report, if expected

Planned: 03/12/2018

Date of final study report

Planned: 15/01/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

eControl Met+_definitivo_sin control de cambios_03.04.2018.pdf(903.57 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

Ethical committee protocol number:P17-205Internal code:DAP-MET-2018-01ESR code:ESR-16-12628

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The primary objective:• To compare the proportion of patients achieving the reduction in HbA1c values of at least 0.5%, a weight reduction of at least 3%, after the addition of a SU, an DPP-4i or an SGLT-2i to the treatment with metformin in patients with T2DM and insufficient glycemic control in the medium-long term, up to a maximum of 24 months of follow-up.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10BA02) metformin

metformin

(A10BB) Sulfonylureas

Sulfonylureas

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

Dipeptidyl peptidase 4 (DPP-4) inhibitors

(A10BK) Sodium-glucose co-transporter 2 (SGLT2) inhibitors

Sodium-glucose co-transporter 2 (SGLT2) inhibitors

Medical condition to be studied

Diabetes mellitus management

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

189776

Study design details

Outcomes

As outcomes, we define the reduction of HbA1c of at least 0.5%, reduction of a weight of at least 3%, as well as occurrence of different side effects after index date for each cohort.

Data analysis plan

Descriptive statistics (Minimum, maximum, mean, standard deviation, frequency, and percentage) of each of the registered variables will be used to describe and evaluate the baseline characteristics of the cohorts. To evaluate

the homogeneity of the groups, it will be calculated the differences between the means and standard deviation with respect to one of the group's pre and post-matching. And homogeneity for categorical variables would be done by comparison of the frequency distribution across levels of the variable.For the main analysis, generalized linear mixed models (GLMM) will be used to evaluate changes in clinical parameters between groups during follow-up. Average changes or reductions in average means per temporal unit will be estimated after treatment. COX regression models will be used to estimate the risk of achieving the combined objective(reduction of HbA1c of at least 0.5%, weight reduction of at least 3% or both) during follow-up.

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

Investigators conflict of interest.pdf(214.29 KB)

Composition of steering group and observers

EUPAS23769-23877.pdf(321.62 KB)

Signed code of conduct checklist

EUPAS23769-23878.pdf(274.76 KB)

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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