Effectiveness in clinical practice versus efficacy of dipeptidyl peptidase-4 inhibitors in clinical trials for type 2 diabetes: protocol for systematic review

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Study Planned

Administrative details

EU PAS number

EUPAS31738

Study ID

32528

DARWIN EU® study

No

Study countries

☐ Portugal

Study status

Planned

Research institutions and networks

Institutions

Association for Innovation and Biomedical Research on Light and Image (AIBILI)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Francisco Batel Marques

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/06/2019

Actual: 24/06/2019

Study start date
Planned: 31/01/2020

Date of final study report
Planned: 31/12/2019

Sources of funding

- Other

More details on funding

AIBILI

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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To compare the results obtained for efficacy and effectiveness endpoints on clinical trials and those obtained from routine clinical practice of DPP4 inhibitors.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

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

Dipeptidyl peptidase 4 (DPP-4) inhibitors

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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

0

Study design details

Outcomes

Efficacy endpoints: mean change from baseline 1) in haemoglobin A1C (HbA1c), 2) in fasting plasma glucose, 3) glucose, 4) in body weight, and number of patients achieving HbA1c<7%. Effectiveness endpoints: all-cause mortality, cardiovascular-related mortality, acute myocardial infarction, stroke, hospitalisations, emergency department visits, amputations, nephropathy and retinopathy.

Data analysis plan

The methodological quality of the RCT and observational studies will be assessed using Downs and Black checklist, while the AMSTAR 2 instrument will be used for the meta-analysis.To compare efficacy results of the DPP4 inhibitors

when used in clinical trials context with their effectiveness in routine clinical practice,meta-analyses will be carried out for premarketing and postmarketing data.For continuous outcomes, the weighted mean differences between the intervention group and the comparator group, with their 95%CI,will be estimated using a random effects model.If a study does not report the SD, this will be calculated from the sample size and the SE or the 95%CI.The risk ratios and the 95%CI will be estimated for dichotomous outcomes, also using a random effects model.Between studies, heterogeneity will be assessed using the I2 statistic.The publication bias will be examined through visual inspection of a funnel plot and statistically evaluated by Egger's regression asymmetry test.

Data management

Data sources

Data sources (types)

Published literature

Other

Data sources (types), other

Systematic literature search in Medline, Embase, Cochrane Controlled Register of Trials and ClinicalTrials.gov.

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