Exploring new treatments and outcomes in type 2 diabetes

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Last updated: 30/05/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/40327

EU PAS number

EUPAS40326

Study ID

40327

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Finland
- ☐ Sweden

United Kingdom

Study description

This study aims to assess the effect of exposure to SGLT2i, GLP1RA and DPP4i drugs in type 2 diabetes. We will assess the effect of these medicines on continuous variable and clinical events in the Scottish Diabetes Register and then in meta-analysis with collaborators internationally. As such this will be a large, population-based observational study, which will look at both effectiveness and safety outcomes.

Study status

Planned

Research institutions and networks

Institutions

University of Edinburgh (UofE)

United Kingdom

First published: 23/11/2018

Last updated: 16/12/2024

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

Steno Diabetes Center Denmark, University of Eastern Finland Finalnd, University of Gothenberg

Sweden, University of Swansea United Kingdom

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Thomas Caparrotta

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/08/2018

Study start date

Planned: 01/08/2021

Date of final study report

Planned: 01/08/2022

Sources of funding

- Non-for-profit organisation (e.g. charity)

More details on funding

Diabetes UK

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)

Safety study (incl. comparative)

Main study objective:

To assess the effect of exposure on - Effectiveness outcomes (CVD surrogate markers and CVD events) - Safety outcomes (various, depending on drug class)

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

(A10BJ) Glucagon-like peptide-1 (GLP-1) analogues

Glucagon-like peptide-1 (GLP-1) analogues

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

Sodium-glucose co-transporter 2 (SGLT2) 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

Hepatic impaired

Renal impaired

Estimated number of subjects

300000

Study design details

Data analysis plan

For continuous variable outcomes we will use: linear mixed effects regression models among those exposed to drug of interest that utilise pre-exposure data to control for the expected within-person trajectories in the outcome of interest in the absence of the drug. In order to control for serial autocorrelation between measurements, all models will be fitted with a continuous autoregressive correlation structure (CAR1), explicitly allowing for correlation between measurements that exponentially decayed the further apart they were in time For clinical event outcomes: Analysis of all event outcomes will use first event only. The effects of exposure on the outcome of interest will be investigated using Poisson-likelihood regression models, with an ever/never and cumulative exposure term included. We will focus our inferences on the significance of the cumulative (dose-response) term.

Data management

Data sources

Data source(s)

SAIL Databank

Data source(s), other

SAIL databank

Data sources (types)

Disease registry

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection

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