An Observational/Non-interventional Evaluation of Subject Outcomes for Type 2 Diabetes Mellitus (T2DM) Subjects Prescribed Dipeptidyl Peptidase-4 Inhibitors (DPP4i), Sodium-glucose Cotransporter-2 Inhibitors (SGLT2i) or Sulphonylureas (SUs) at First Intensification

First published: 27/03/2019

Last updated: 25/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS28930

Study ID

38608

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This is an observational, non-interventional, retrospective cohort study of patients with T2DM. This study will evaluate the change in patient’s hemoglobin A1c (HbA1c) level from baseline at 6- and 12-months when a second drug is added to a patient’s treatment regimen using data from real-world clinical practice. To determine the impact of baseline HbA1c level on outcomes, data will be analysed by treatment and by strata defined by patient’s baseline HbA1c levels. Patients diagnosed with T2DM between 01 January 2002 and 31 December 2017 with a prescription for metformin followed by addition of dipeptidyl peptidase-4 inhibitors (DPP4i), sodium-glucose cotransporter-2 inhibitors (SGLT2i) or sulphonylureas (SU) will be observed with results being reported separately for each of these three groups. Retrospective data for each patient will be extracted for a 6-month pre-index period and up to 15-years of follow-up. Index date is defined as the date of intensification of therapy. Data will be available for inclusion in the study across the period from 01 January 2001 to 31 December 2017. Data will be collected up to death, loss to follow-up or end of study period, whichever occurs first. The study will use electronic primary care medical records contained within the Clinical Practices Research Datalink (CPRD) GOLD dataset from primary care sites within the United Kingdom (UK). The overall duration of the study is approximately 6 months.

Study status

Finalised

Contact details

Study institution contact

Minesh Unadkat trialdisclosures@takeda.com

Study contact

trialdisclosures@takeda.com

Primary lead investigator

Marc Evans

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2019

Actual: 01/03/2019

Study start date

Planned: 01/11/2019

Actual: 01/11/2019

Data analysis start date

Planned: 15/11/2019

Actual: 15/11/2019

Date of interim report, if expected

Planned: 31/12/2019

Date of final study report

Planned: 31/12/2019

Actual: 31/12/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The primary objective is to estimate the change in HbA1c post-baseline (that is addition of an SU, DPP-4i or SGLT2i to metformin) stratified by baseline HbA1c, at Months 6 and 12.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

Adult patients with Type 2 diabetes mellitus (T2DM) on the CPRD GOLD database between 01 January 2002 to 31 December 2017.

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

Other

Special population of interest, other

Type 2 diabetes mellitus patients

Estimated number of subjects

40000

Study design details

Outcomes

There is one primary outcome which evaluates HbA1c change from baseline to Months 6 and 12. The secondary outcomes include: evaluation of change from baseline in body weight at Months 6 and 12, discontinuation rates at Months 6 and 12 post-baseline, treatment intensification at Months 6 and 12 post-baseline, mean medicines possession ratio (MRP) across medication, medication persistence, urinary tract infection (UTI) rates, hypoglycaemic episode counts and rates of adverse events.

Data analysis plan

Mixed-effects regression modelling will be used to test for significant differences in changes in HbA1c levels from baseline at 6 and 12 months for 3 different medications. Models will be fitted to data to adjust for the effect of observed covariates including:demographic, clinical factors, other prescriptions, comorbidities and centre effects. Appropriate regression techniques will be used in accordance with the assumed distribution of outcome variable. Descriptive statistics will be used to characterise patterns and interrelationships between different factors. If appropriate, models of rates will be estimated using survival analysis,and binary outcomes will be estimated using logistic or probit regression. Transformation of outcome, or alternatives such as Poisson and negative binomial regression may be used in case of non-normally distributed outcomes. Akaike's Information Criteria may be used to inform variable inclusion.

Documents

Study results

T2DM-5002 - ENCEPP Results.pdf (647.64 KB)

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)

Clinical Practice Research Datalink

Data source(s), other

CPRD

Data sources (types)

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