Evaluating the cost and clinical outcomes of changing type 2 diabetes mellitus patients from current DPP-4 inhibitor treatment to alogliptin in a primary care setting

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Study Finalised

Administrative details

EU PAS number

EUPAS29153

Study ID

36281

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This is an retrospective, observational study to evaluate the cost and clinical outcomes of changing type 2 diabetes mellitus patients from current DPP-4 inhibitor treatment to alogliptin in a primary care setting. The study population include all T2DM patients who have had therapy changed from another DPP-4 inhibitor to alogliptin, in combination with other hypoglycaemic agent(s) in primary care.

Study status

Finalised

Research institutions and networks

Institutions

Dr David Strain

Networks

UK Clinical Research Network

Contact details

Study institution contact

David Strain trialdisclosures@takeda.com

Study contact

trialdisclosures@takeda.com

Primary lead investigator

David Strain

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/02/2018

Actual: 03/02/2018

Study start date

Planned: 09/03/2018

Actual: 09/03/2018

Date of final study report

Planned: 29/06/2018

Actual: 29/06/2018

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

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of the study is to retrospectively estimate the clinical impact of changing T2DM patients from current DPP-4 inhibitor to alogliptin,

assessed by the unadjusted and adjusted change in HbA1c between pre and post switch measurements and including deviation from HbA1c trajectory.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective, observational study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

ALOGLIPTIN

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

The study population include all T2DM patients who have had therapy changed from another DPP-4 inhibitor to alogliptin, in combination with other hypoglycaemic agent(s) in primary care.

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

1.000

Study design details

Outcomes

To capture the primary outcome, HbA1c measurements (% HbA1c numeric value and date recorded DD/MM/YYY) will be collected for the pre and post-index periods. The index date will also be recorded for each patient. The secondary outcome will assess impact on direct prescribing costs resulting from changing T2DM patients from current DPP4 inhibitor to alogliptin within licenced indications, dose and frequency of alogliptin, Alogliptin stop date post index, Start date of anti-diabetic therapy rescue medication, Anti-diabetic medication and dose added on rescue, Changes to existing anti-diabetic medication.

Data analysis plan

Continuous variables will be described by their mean, standard deviation, median, quartiles 1 and 3, extreme values (minimum and maximum), 95% confidence intervals and frequency of missing data. Categorical variables will be described by their frequency and percentage of the sample population. A generalised linear mixed effects model will be used to assess for any change in HbA1c trajectory as a function of switching to alogliptin. Fisher's exact tests will be used for binary categorical variables and Chi-squared tests will be used for (unordered) categorical variables. A p-value of less than 0.05 will be considered statistically significant.

Documents

Study results

Alogliptin-5010_Strain et al_What Next After Metformin_Diabetes Ther 2020.pdf (186.18 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 sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Retrospective 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

Unknown