Efficiency and Safety of Six Month Oglition® Therapy of Patients with Diabetes Mellitus type 2

First published: 11/04/2016

Last updated: 29/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS13117

Study ID

17136

DARWIN EU® study

No

Study countries

Serbia

Study description

Primary goal:Monitoring of efficiency and safety of the drug Oglition® in therapy of diabetes mellitus type 2 in the period of 6 months.Secondary goals:Monitoring of efficiency and safety of the drug Oglition® in the subgroup of patients on the previous monotherapy by metformin.Monitoring of efficiency and safety of the drug Oglition® in the subgroup of patients on the previous dual therapy by metformin and glimepiride.

Study status

Finalised

Research institutions and networks

Institutions

Actavis

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 5 centers are involved in the study

Contact details

Study institution contact

Snezana Subotic snezana.subotic@actavis.com

Study contact

snezana.subotic@actavis.com

Primary lead investigator

Snezana Subotic

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/11/2014

Actual: 01/11/2014

Study start date

Planned: 01/05/2015

Actual: 01/05/2015

Date of final study report

Planned: 30/09/2016

Actual: 08/01/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Actavis

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Other

If ‘other’, further details on the scope of the study

Efficacy

Data collection methods:

Primary data collection

Main study objective:

Obtain information on efficacy and safety.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Oglition

Population studied

Short description of the study population

Adult patients with Diabetes Mellitus type 2 with HbA1c values ranging from 7% to 9.5% while on monotherapy by metformin (in the dose of 1 or 2 g), or on dual therapy by metformin (in dose of 1 or 2 g) and glimepiride (in dose of 2-4 g).

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

Diabetes mellitus patients

Estimated number of subjects

440

Study design details

Outcomes

Monitoring of change of level of HbA1C before and during therapy by pioglitazone·Determining of glucose level on an empty stomach before and during therapy by pioglitazone·Monitoring of frequency of occurrence of hypoglycaemiaMonitoring of satisfaction with therapy, Monitoring of efficiency and safety of the drug Oglition® in the subgroup of patients on the previous monotherapy by metformin.Monitoring of efficiency and safety of the drug Oglition® in the subgroup of patients on the previous dual therapy by metformin and glimepiride.

Data analysis plan

measures of risk

Documents

Study results

Oglition final study report.pdf (1.55 MB)

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)

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

Unknown