A 6-month, Multicenter, single-Arm, observational study with a 6-month extension evaluating patient-reported outcomes of insulin Glargine 300 U/mL (Gla-300) in basal/bolus-treated people with T2 diabetes on therapy in a rEal world setting (MAGE study) (PRO of Insulin Glargine 300 U/mL in T2 diabetes in)

First published: 17/02/2017

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17150

Study ID

45649

DARWIN EU® study

No

Study countries

☐ Belgium

Study description

This is a 6-months, multicenter, prospective, single-arm observational Belgian study with Gla-300 with a 6-months extension.The study is non-interventional on the therapeutic strategy.Patients serve as their own control.The inclusion procedure and documentation of data will not affect daily prescription routines, and the ADA/EASD position statement regarding treatment of type 2 diabetes will be respected.Patients fulfilling the study criteria will be asked to participate to this study. They will be asked to sign written consent after the study being explained and before any study related procedure. They will be in the study for at least 6 months, after which they will be proposed to continue in the extension study for another 6 months. If a patient discontinues, then the reason for it will be documented.After the baseline visit, it is expected that 2 visits with a possibility of 2 extra visits if a patient agrees to the extension study, will be scheduled by the physician. Measurements will therefore be taken at 3 and 6 months (the main study) and at 9 and 12 months (the extension study).Additional contacts if deemed necessary by the investigator or as in current practice are allowed.

Study status

Finalised

Research institutions and networks

Institutions

Prof. Dr. C. Mathieu UZ Gasthuisberg Leuven, Dr. P. Kleynen CHU St Pierre Brussels, Dr. Fabienne Liénart CHU Tivoli La Louvière, Dr. E. Heyns AZ Groeninge Kortrijk, Dr. A. Verhaegen AZ Jan Palfijn Merksem, Dr. L. Derdelinckx Clinique Saint-Luc Bouge, Prof. I. Colin CHR Mons-Hainaut – Site St-Joseph Mons, Dr. P. Abrams GZA ziekenhuizen Wilrijk, Dr. V. Preumont CU St Luc - Brussels, Dr Ramon (A Paré) + Dr Liénart (St Jean) CHU A. Paré (Mons) + St Jean (Brussels)

Contact details

Study institution contact

Kathy Alexandre kathy.alexandre@sanofi.com

Study contact

kathy.alexandre@sanofi.com

Primary lead investigator

André Prof. Dr. Scheen

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 19/04/2016

Study start date
Actual: 31/05/2016

Date of final study report
Planned: 29/03/2019

Actual: 03/09/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi Belgium

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Evaluation of patient-reported outcomes

Data collection methods:

Primary data collection

Main study objective:

The primary objective: to demonstrate a change of at least 2 points in the DTSQs Total Treatment Satisfaction score from baseline to month 6 in patients with type 2 diabetes treated with Gla-300 in routine care.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multicenter, prospective, single-arm observational Belgian study

Study drug and medical condition

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

INSULIN GLARGINE

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

Patients with type 2 diabetes who, prior to Gla-300 treatment, were already on insulin treatment for at least 6 months, were included.

The inclusion criteria of the main study were:

• ≥18 years;

• T2DM (> 1 year);

• HbA1c 7.0–10.0%;

• basal-bolus (BB) with 4 or 5 injections for at least 6 months;

• metformin (MET) could be used as background OAD;

• no prior therapy with Gla-300;

• reason identified by physician and/or patient to start Gla-300 (hypoglycemia – nr. of hypoglycemic events or fear of hypoglycemia; insulin dose – need for less

volume; treatment – flexibility in injection time; HbA1c – not reaching treatment goals [<7%, as defined by the ADA/EASD position statement]; any other reason);

• willingness/capability to self-manage titration algorithm;

• willingness to fill in 5 PRO questionnaires;

• and signed informed consent

The inclusion criteria of the extension period were: patient having participated in the main study and signed informed consent

The exclusion criteria (main study and extension period) were:

• pregnancy or pregnancy wish within next 7 months;

• T1DM;

• other types of diabetes than T2DM (ex. secondary to pancreatitis);

• oral corticosteroid therapy;

• life expectancy < 1 year;

• and OAD other than MET.

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

Study design details

Outcomes

The primary endpoint is the change in DTSQs total treatment satisfaction score from baseline to month 6, Reason(s) for starting with Gla-300:o Hypoglycemia – nr. of hypoglycemic events or fear of hypoglycemiao Insulin dose – need for less volumeo Treatment - flexibilityo HbA1c – not reaching treatment goals (<7%, as defined by the ADA/EASD position statement)o Any other reason + others secondary outcomes

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Data analysis plan

Primary analysis : The limit central theorem will be invoked on the basis of the n° of patients (>30) to assume that the normality of the primary endpoint is achieved. The primary endpoint will be analyzed using a paired Student’s t test. A p value lower than 5% will be considered statistically significant.Descriptive statistics (mean, median, standard deviation, minimum and maximum) will also be used to characterize the primary endpoint. The analysis of secondary endpoints will be mainly descriptive. For all continuous variables the following parameters will be provided: mean, standard deviation, minimum, 1st quartile, median, 3rd quartile, maximum, number of observations and number of missing observations.Discrete binary, nominal and ordinal variables will be described by n° of observed values (N), absolute (n) and relative (%) frequencies, n° of missing values. The proportions corresponding to the principal endpoints will be accompanied by their exact 95% confidence intervals.

Documents

Study results

Clinical Study Report_MAGE_Sanofi_Erratum 16072019.pdf (186.09 KB)

MAGE_CSR synopsis_12Feb2019.pdf (172.76 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)

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