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Efficacy and safety of using insulin glargine 300 U/mL in patients on advanced insulin therapy with type 1 or type 2 diabetes failing to achieve their glycemic targets. The Toujeo-Neo trial.

Submission date
26/02/2019

Recruitment status
No longer recruiting

Registration date
27/02/2019

Overall study status
Completed

Last Edited
27/09/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
All people with diabetes need insulin, either directly after diagnosis in patients with type 1 diabetes or at later disease stages in people with type 2 diabetes. There are two kind of insulin available to imitate the body's missing insulin supply: basal insulin to cover the basal need for insulin and mealtime insulin to cover the shortly elevated need after meal intake. Advanced insulin therapies using one or two shots of mealtime insulin together with basal insulin are used in long-lasting type 2 diabetes and therapies with three shots of mealtime insulin are used in long-lasting type 2 diabetes as well as in type 1 diabetes. To take insulin goes hand in hand with hypoglycemia, an unwanted state of too low blood sugar with several symptoms, sometimes even including fainting and coma. Therefore, fear of hypoglycemia often prevents people with diabetes to achieve their blood sugar targets. On the other hand it is very important for patients with diabetes to reach their blood sugar targets to avoid late-stage complications like kidney disease, eye disorders and cardiovascular diseases. Several newer types of insulins have been developed, which reduce the risk for hypoglycemia compared to older types of insulin. The aim of this study is to find out, if switching from any other basal insulin to insulin glargine 300 units per milliliter, a newer basal insulin, allows more people with type 1 or type 2 diabetes on advanced insulin therapies (using a basal and a mealtime insulin) to reach their blood sugar targets without increasing the risk of hypoglycemia in daily clinical practice.

Who can participate?
Adults at or over the age of 18 years with type 1 or type 2 diabetes who use advanced insulin therapies (basal and mealtime insulin) and are treated by a German physician.

What does the study involve?
Participants are elected by their treating physician to join this study, if the physician had already decided to switch their basal insulin to insulin glargine 300 units per milliliter independent of the participation in this study. Participants will be treated by their physician as usual and will visit their doctor in the usual time intervals (in Germany usually every three months for diabetes

patients). The physician will document several parameters at the first visit, when the basal insulin is switched, and at least 6 and 12 months thereafter. The study lasts one year in total. The participants are asked to answer a diabetes treatment satisfaction questionnaire at the first visit and at the visit 12 months thereafter.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit or risk to those taking part, because this is a non-interventional study which means that patients are treated as they would be without participation in this study. However, the results of this study will add to the knowledge of how insulin glargine 300 units per milliliter is used in daily clinical practice and how its use in combination with mealtime insulins can be improved.

Where is the study run from?
The Toujeo-Neo study is being run by Sanofi-Aventis Deutschland GmbH and takes place in diabetologists' and general practioners', family physicians' and internists' practices all over Germany, where people with type 1 and type 2 diabetes are treated.

When is the study starting and now long is it expected to run for?
August 2015 to March 2017

Who is funding the study?
Sanofi-Aventis Deutschland GmbH (Germany)

Who is the main contact?
Dr. Stefan Pscherer, chief physician of Clinic of Internal Medicine III, Diabetology and Nephrology, Sophien- und Hufeland-Klinikum gGmbH, Henry-van-de-Velde-Str. 2, D-99425 Weimar, Germany, email: S.Pscherer@klinikum-weimar.de

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
GLARGL07591

Study information

Scientific Title
Assessment of Treatment Efficacy and Safety when switching the Basal component of any BOTplus or Basal-Bolus Regimen in Patients Failing to Reach Treatment Targets to Insulin glargine U300

Acronym
Toujeo-Neo

Study objectives
The aim of this non-interventional study (NIS) was to document the treatment effectiveness and safety after 6 and 12 months for diabetes patients who switched from a basal Insulin supported oral therapy with additional 1-2 prandial Insulin injections (BOTplus; type 2 diabetes mellitus) or a basal-bolus therapy (BBT; type 1 or type 2 diabetes mellitus; T1DM, T2DM) with any basal insulin other than insulin glargine 300 U/mL to a BOTplus or BBT with insulin glargine 300 U/mL under use in real-life conditions in daily clinical practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/07/2015, Ethik-Kommission der Bayerischen Landesärztekammer/Ethical committee of the state medical council of Bavaria (Mühlbaurstr.16, D-81677, Munich; + 49 89 4147-165; ethikkommission@blaek.de), ref: 15049

Study design
Non-interventional open-label multi-center single-arm prospective observational study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Type 1 and type 2 diabetes mellitus in adult patients requiring insulin therapy.

Interventions
All data were collected three times: at baseline, approximately 6 and approximately 12 months after starting insulin glargine 300 U/mL therapy. Baseline documentation (documentation 1) had to start immediately after switching to insulin glargine 300 U/mL from any other basal insulin after failing to achieve the glycemic targets on a pre-existing BOTplus (T2DM) or BBT (T1DM and T2DM) treatment. This had to occur after the physician had independently of the participation in this study decided to prescribe insulin glargine 300 U/mL and when thereafter the physician and the patient had decided the participation of the latter in this study. Next measurements were documented approximately 6 months thereafter (documentation 2) and the last measurements were documented approximately 12 months thereafter (documentation 3). Besides this, all FBG measurements available were collected on a monthly basis asking for documentation of changes during the last four weeks each month. Also, dosing information was captured every month; i.e. actual dose and frequency of dose changes during the last four weeks. Data had to be generated during the daily clinical routine of the physicians. Any change in the patient's antidiabetic therapy regimen was strictly left at the physician's discretion. No therapeutic decision of the physician should have been based upon participation in this NIS. Titration algorithm was also left at the investigator's discretion.
Participating physicians were distributed equally all over Germany to allow for a representative sample of German T1DM and T2DM patients switching their basal insulin component of their BOTplus or BBT regimen.
In order to allow for a valid statistical analysis even in smaller subgroups of patients (as distribution within the predefined subgroups may not be equal), it was planned to document and analyze about 2,500 patients. The planned number of participating sites was 540.
Participating doctors were mostly to be diabetologists, as the kind of physician who usually follow-up basal plus prandial insulin therapy in T1DM and T2DM patients in Germany. Also, general practitioners, family physicians and internists (office based) were to be included in the study, if they treat advanced T2DM and T1DM patients. The practices were to be distributed equally all over Germany to allow for geographical representativeness.

Intervention Type
Other

Primary outcome measure
Duration (persistency) of response defined as time from start of response to end of response. Beginning of response was defined by time of the first of at least two FBG values below or equal to 110 mg/dL or time of first HbA1c below or equal to predefined individual target value whichever occurred first. End of response was defined as one of the following:
- the second FBG value >110 mg/dL (>6.1 mmol/L) after start of FBG response or
- the first HbA1c value above the individual predefined target or
- change to another form of insulin therapy or change of basal insulin.

Secondary outcome measures
1. Absolute change in HbA1c from baseline to 6 months to 12 months
2. Absolute change in FBG from baseline to 6 months to 12 months
3. Response rate 6 and 12 months after start of insulin glargine 300 U/mL treatment defined by:

- Reaching two FBG values below or equal to 110 mg/dL or at least once the predefined individual HbA1c target value or
- Reaching at least one HbA1c value equal or less to the predefined individual HbA1c target value OR
- Reaching two FBG values below or equal to 110 mg/dL or
- Reaching two FBG values below or equal to 110 mg/dL and at least once the predefined individual HbA1c target value.

4. Time from start of insulin glargine 300 U/mL treatment to response for each of the response endpoints
5. Incidence rates and rates per patient-year were calculated for symptomatic, confirmed symptomatic, nocturnal, severe, and severe nocturnal hypoglycemia as reported in the electronic Case Report Form (eCRF). Confirmation of symptomatic hypoglycemia was defined as self-measured blood glucose (SMBG) measurement below or equal to 70 mg/dL. Severe hypoglycemia was defined as necessity of the assistance of another person or an SMBG measurement of below or equal to 56 mg/dL. Nocturnal hypoglycemia occurring during the night (approximately 10pm-6am), while the patient was asleep (symptomatic or confirmed by SMBG measurement below or equal to 70 mg/dL). Severe nocturnal hypoglycemia was defined as those nocturnal hypoglycemia fulfilling the Definition of severe hypoglycemia. 95% CIs for incidence rates were calculated according to Clopper-Pearson. Rates per patient-year were calculated as a cumulative number of hypoglycemia events for all patients divided by the cumulative duration of insulin glargine 300 U/mL therapy in years, whereas patients with missing treatment duration or missing number of hypoglycemic events were excluded.
6. Absolute change in the 4-point blood glucose profile from baseline to 6 months to 12 months
7. Absolute change in body weight from baseline to 6 months to 12 months
8. Absolute change in daily insulin doses (number of units and number of units per kg body weight [BW]) and number of dose modifications per visit.
9. Values and absolute changes for blood lipids (triglycerides, high-density Lipoprotein [HDL], low-density Lipoprotein [LDL] and total cholesterol) from baseline to 6 months to 12 months
10. Type of LLT overall and by LDL subgroups (<70 mg/dL, <100 mg/dL, 100-190 mg/dL, >190 mg /dL at respective visit). An intensification of LLT was defined as administration of an additional LLT drug compared to baseline, or a higher dosing of statin, i.e. change from moderate at one visit to intensive at a following visit.
11. Patient's treatment satisfaction, measured by using the Diabetes Treatment Satisfaction Questionnaire (DTSQs) instrument is comprised of eight items. For scoring, six of these items were summed to produce a measure of satisfaction with treatment. The remaining two items (perceived frequency of hyperglycemia and perceived frequency of hypoglycemia) were treated individually. Measured at baseline, 6 months, and 12 months.
12. Safety parameters were incidences of adverse events (AE), related AEs, serious adverse events (SAE), related SAEs and fatal AEs.

Overall study start date
02/12/2014

Completion date
29/03/2017

Eligibility

Key inclusion criteria
1. Patients with type 1 diabetes (basal-bolus insulin therapy) or type 2 diabetes (basal insulin plus 1-2x prandial insulin and oral antidiabetic drugs or basal-bolus insulin therapy) with any

basal insulin except insulin glargine 300 U/mL.
2. Adults and Seniors: Age at least 18 years, no upper age limit.
3. HbA1c between 7.5% to 10.0%.
4. Fasting blood glucose > 130 mg/dL.
5. Ability and willingness to perform blood glucose self-monitoring.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2500 participants

Key exclusion criteria
1. Contraindications for a therapy with insulin glargine 300 U/mL.
2. Patients receiving oral antidiabetic drug therapy only.
3. Patients receiving basal insulin and oral antidiabetic drugs without prandial insulin.
4. Patients with known cancer disease.
5. Pregnancy.
6. Drug or alcohol abuse.
7. Dementia or general incapacity to understand the content of the observational study.

Date of first enrolment
11/08/2015

Date of final enrolment
31/01/2016

Locations

Countries of recruitment
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Funder(s)

Funder type
Industry

Funder Name
Sanofi-Aventis Deutschland GmbH

Results and Publications

Publication and dissemination plan
Full publications planned in high-impact peer-reviewed journals:
2 full publications (results for type 1 diabetes and results for type 2 diabetes) planned for Q2 /2019.
4 full paper on sub group analyses (age groups, responder, each in type 1 diabetes and type 2 diabetes) are planned for end of 2019.

Intention to publish date
30/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Poster results	Pscherer S, Pfohl M, Anderten H, Pegelow K, Seufert J. Nicht-interventionelle Studie zur Untersuchung der Effizienz des Wechsels der Basalinsulinkomponente bei einer BOTplus oder intensivierten Insulintherapie (ICT) zu Insulin glargin 0 E/ml bei Typ-1- und Typ-2-Diabetespatienten mit inadäquater glykämischer Kontrolle. Diabetologie & Stoffwechsel 2016; 11 (Suppl. 1): Abstr. P220. Presented as poster at the 51rst Annual Meeting of the German Diabetes Association (DDG) at 05.05.2016 in Berlin, Germany. Available at:	05/05/2016		No	No
Poster results	Fritsche A, Pscherer S, Pfohl M, Anderten H, Pegelow K, Seufert J. Umstellung des Basalinsulins auf Insulin glargin 0 E/ml (Gla-0) nach Versagen der Basis-Bolus-Therapie (ICT) mit einem anderen Basalinsulin verbesserte bei Typ-1-Diabetespatienten die Blutzucker-Einstellung – 6-Monats-Ergebnisse der Toujeo-Neo-T1DM-Studie. Diabetologie & Stoffwechsel 2018; 13 (Suppl. 1): S61, Abstract P181. Presented as poster at the 53rst Annual Meeting of the German Diabetes Association (DDG) at 11.05.2018 in Berlin, Germany. Available at: Pscherer S, Pfohl M, Fritsche A, Anderten H, Pegelow K, Seufert J. Umstellung des Basalinsulins auf Insulin glargin 0 E/ml (Gla-0) nach	11/05/2018		No	No

Poster results	Versagen einer Basis-Bolus- (ICT) oder einer basalunterstützten oralen Therapie mit einmal täglich prandialem Insulin (BOTplus) mit einem anderen Basalinsulin verbesserte bei Typ-2-Diabetespatienten die glykämische Kontrolle – 6-Monats-Ergebnisse der Toujeo-Neo-T2DM-Studie. Diabetologie & Stoffwechsel 2018; 13 (Suppl. 1): S51-S52, Abstract P153. Presented as poster at the 53rst Annual Meeting of the German Diabetes Association (DDG) at 11.05.2018 in Berlin, Germany. Available at:	11/05/2018		No	No
Abstract results	Pscherer S, Fritsche A, Anderten H, Pegelow K, Seufert J, Pfohl M. Switching to Insulin Glargine 0 U/mL (Gla-0) after Failure of Advanced Insulin Therapy (IT) with Other Basal Insulins (BI) in Patients (Pts) with Type 2 Diabetes (T2DM) Improved Glycemic Control. Diabetes 2018; 67 (Suppl. 1): Abstract 2288-PUB (Published only). Available at:	23/06/2018		No	No
Poster results	Fritsche A, Pscherer S, Anderten H, Pegelow K, Seufert J, Pfohl M. Switching to Insulin Glargine 0 U/mL (Gla-0) Improves Glycemic Control After Failure of Basal-Bolus Therapy (BBT) With Other Basal Insulins (BI) in patients (pts) with Type 1 Diabetes (T1DM). Diabetes 2018; 67 (Suppl. 1): Abstract 1031-P. Presented as poster at the 78th Scientific Sessions of the American Diabetes Association at 23.06.2018 in Orlando, FL, USA. Available at:	23/06/2018		No	No
Protocol file	version 1.0	06/05/2015	27/09/2022	No	No