

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/02/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/09/2022	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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 practitioners', 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 how 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

Contact information

Type(s)

Scientific

Contact name

Dr Katrin Pegelow

Contact details

Sanofi-Aventis Deutschland GmbH

Potsdamer Str. 8

Berlin

Germany

D-10785

+49 (0)30 2575 2920

Katrin.Pegelow@sanofi.com

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 (Mühlbauerstr.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 (persistence) 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

Germany

Study participating centre

Herr Dr. Stefan Pscherer

Germany

99425

Study participating centre

Herr Dr. Frank Ackermann
Germany
06108

Study participating centre
Frau Dr. Susanne Adler
Germany
33332

Study participating centre
Herr Dr. Hasan Alawi
Germany
66740

Study participating centre
Herr Dr. Heiko Ambrosch
Germany
06712

Study participating centre
Frau Dr. Steffi Appelt
Germany
97421

Study participating centre
Frau Dr. Kathrin Auerbach
Germany
04779

Study participating centre
Herr Modjtaba Barghi
Germany
12347

Study participating centre

Herr Jürgen Bartlewski

Germany

76139

Study participating centre

Frau Dr. Anna BartnikMikuta

Germany

92237

Study participating centre

Herr Dr. Bert Basan

Germany

18209

Study participating centre

Herr Dr. Bernd Becker

Germany

45355

Study participating centre

Herr Dr. Sven Becker

Germany

99085

Study participating centre

Frau Dr. Kerstin Benecke

Germany

39104

Study participating centre

Herr Dr. Matthias Benecke

Germany

06122

Study participating centre

Herr Dr. Dirk Berger

Germany

31139

Study participating centre

Herr Dr. Peter Berndt

Germany

45309

Study participating centre

Herr Dr. Tasso Bieler

Germany

01587

Study participating centre

Herr Dr. Ralph Achim Bierwirth

Germany

45138

Study participating centre

Herr Igor Bolsun

Germany

89073

Study participating centre

Herr Dr. Beqir Brahimi

Germany

47906

Study participating centre

Herr Dr. Markus Braun

Germany

84489

Study participating centre

Frau Dr. Daniela Brugger

Germany

83278

Study participating centre

Herr Dr. Peter Bühler

Germany

88430

Study participating centre

Herr Dr. Thomas Bulang

Germany

02625

Study participating centre

Herr Dr. Klaus Burkhardt

Germany

91781

Study participating centre

Herr Dr. Ronny Casneuf

Germany

30880

Study participating centre

Frau ReginaMonika Chmielewski

Germany

58675

Study participating centre

Frau Maren Dehne

Germany

23879

Study participating centre

Frau Dr. Iris DonatiHirsch

Germany

44137

Study participating centre

Herr Dr. Markus Eidenmüller

Germany

35037

Study participating centre

Herr Dr. Volker Eissing

Germany

26871

Study participating centre

Frau Dr. Annette Engelhardt

Germany

99610

Study participating centre

Frau Dr. Friedlinde Ernst

Germany

87439

Study participating centre

Herr Dr. FranzRudolf Fendler

Germany

30171

Study participating centre

Frau Manuela FettigKillat

Germany

76661

Study participating centre

Herr Dr. Albrecht Fießelmann

Germany

13597

Study participating centre

Herr Dr. Ulrich Flintzer

Germany

17033

Study participating centre

Herr Frank Franzmann

Germany

32549

Study participating centre

Frau Dr. Verena Fuhrmann

Germany

07545

Study participating centre

Herr Dr. Alexander Garcia Godelmann

Germany

55130

Study participating centre

Herr Dr. Gregor Gauer

Germany

01612

Study participating centre

Frau Sonja Gericke

Germany

19348

Study participating centre

Herr Dr. Peter Geßner

Germany

76149

Study participating centre

Herr Dr. Sebastian GlüerFuchs

Germany

30900

Study participating centre

Herr Dr. RainerChristian Görne

Germany

67433

Study participating centre

Herr Kai Götte

Germany

61381

Study participating centre

Herr Dr. Detlef Götze

Germany

39120

Study participating centre

Herr Volkart Güntsch

Germany

19057

Study participating centre

Herr Dirk Haaser

Germany

01309

Study participating centre

Herr Andreas Hain

Germany

36266

Study participating centre

Herr Dr. Peter Hainzinger

Germany

85057

Study participating centre

Herr Dr. Dirk Hennig

Germany

01662

Study participating centre

Frau Dr. Kerstin HerrmannBenecke

Germany

06122

Study participating centre

Herr Dr. Joachim Hesse

Germany

19370

Study participating centre

Herr Dr. Christoph Heyer

Germany

41747

Study participating centre

Frau Dr. Henrike Hilbig

Germany

30165

Study participating centre

Herr Dr. Roger Hladik

Germany

67063

Study participating centre

Herr Dr. HansDieter Hoffmann

Germany

58706

Study participating centre

Herr Dr. Gerd Hollmann

Germany

13439

Study participating centre

Frau Susanne HöltzRöhrig

Germany

55624

Study participating centre

Frau Dr. Birgit HöneRömmmer

Germany

04299

Study participating centre

Frau Dr. Irina Hort

Germany

10318

Study participating centre

Herr Christoph Hummel

Germany

33602

Study participating centre

Herr Dr. Michael Karl Huptas

Germany

45307

Study participating centre

Herr Dr. Sebastian Huptas

Germany

45307

Study participating centre

Herr Clemens Huth

Germany

47929

Study participating centre

Herr Professor Dr. HansDieter Janisch

Germany

91052

Study participating centre

Herr Dr. HansJoachim Jonderko

Germany

76135

Study participating centre

Herr Dr. HansPeter Kempe

Germany

67059

Study participating centre

Herr Professor Dr. Werner Kern

Germany

89073

Study participating centre

Frau Dr. Stephanie Kieu

Germany

26388

Study participating centre

Herr Dr. Andreas Kirsten

Germany

01129

Study participating centre

Herr Dr. Gerhard Klausmann

Germany

63739

Study participating centre

Herr Dr. Carsten Klugewitz

Germany

45277

Study participating centre

Herr Dr. Karsten Knöbel

Germany

94315

Study participating centre

Frau Dr. Nicole Koch

Germany

22041

Study participating centre

Herr Dr. Thorsten Koch

Germany

22041

Study participating centre

Herr Andreas Kochan

Germany

02826

Study participating centre

Herr Dr. Wolfgang Kohn

Germany

13086

Study participating centre

Frau Dr. Kerstin König

Germany

59174

Study participating centre

Herr Dr. Günter Kraus

Germany

96117

Study participating centre

Frau Katrin Krause

Germany

06366

Study participating centre

Frau Irmhild Krüger

Germany

16928

Study participating centre

Frau Dr. Kerstin Kux

Germany

49124

Study participating centre

Herr Dr. Benedict Lacner

Germany

45468

Study participating centre

Herr Dr. Bernhard Landers

Germany

56727

Study participating centre

Herr Dr. Jürgen Landschulze

Germany

07768

Study participating centre

Frau Dr. Vera Lang

Germany

91207

Study participating centre

Herr Hendrik Lange

Germany

07570

Study participating centre

Herr Dr. Harald Letterer

Germany

29459

Study participating centre

Herr Privatdozent Dr. Ulrich Lotze

Germany

06556

Study participating centre

Frau Dr. Jenny LuongThanh

Germany

26388

Study participating centre

Herr Dr. Lam LuongThanh

Germany

26388

Study participating centre

Frau Dr. Cornelia Marck

Germany

35415

Study participating centre

Herr Dr. Ekkehard Martin

Germany

38165

Study participating centre

Herr Dr. Peter Mayr

Germany

78333

Study participating centre

Herr Dr. Claus Mees

Germany

67063

Study participating centre

Frau Dr. Martina MeierHöfig

Germany

24796

Study participating centre

Frau Peggy Meyer

Germany

13086

Study participating centre

Herr Francesco Michelini

Germany

41472

Study participating centre

Herr Dr. Uwe Milbradt

Germany

39387

Study participating centre

Herr Dr. Rainer Möllmann

Germany

47799

Study participating centre

Herr Dr. Joachim Müller

Germany

97421

Study participating centre

Frau Gabriele MüllerHunold

Germany

38368

Study participating centre

Herr Dr. Axel Müllhofer

Germany

88400

Study participating centre

Frau Dr. Manuela Nader

Germany

82110

Study participating centre

Herr Dr. Rainer Naus

Germany

87435

Study participating centre

Herr Dr. Olaf Ney

Germany

31535

Study participating centre

Herr Michael Nowotny

Germany

02763

Study participating centre

Frau Dr. Katrin Ohde

Germany

45329

Study participating centre

Herr Dr. Tobias Ohde

Germany

45329

Study participating centre

Frau Dr. Silke OttoHagemann

Germany

49377

Study participating centre

Herr Dr. Andreas Patzelt

Germany

44892

Study participating centre

Herr Dr. Johannes Peters

Germany

50126

Study participating centre

Herr Dr. Gert Pfundt

Germany

55130

Study participating centre

Herr Dr. Eberhard Politz

Germany

38518

Study participating centre

Frau Maria Pollok

Germany

58675

Study participating centre

Frau Stefanie Rasfeld

Germany

98574

Study participating centre

Herr Björn Reißmann

Germany

58730

Study participating centre

Frau Dr. Uta Rieger

Germany

14482

Study participating centre

Herr Dr. Uwe Ritzel

Germany

26384

Study participating centre

Herr Dr. Tobias Rückert

Germany

30165

Study participating centre

Frau Dr. Emilia Ruff

Germany

97980

Study participating centre

Frau Dr. Ursula Ruthe

Germany

14532

Study participating centre

Herr Dr. Oliver Sauer

Germany

02826

Study participating centre

Frau Dr. Astrid Sawistowsky

Germany

04249

Study participating centre

Herr Dr. Jörg Schaper

Germany

86470

Study participating centre

Herr Privatdozent Dr. Stephan Scharla

Germany

83435

Study participating centre

Herr Edgar Schaubert

Germany

52457

Study participating centre

Herr Dr. Thomas Schaum

Germany

23758

Study participating centre

Herr Dr. Reinhard Schaupp

Germany

97762

Study participating centre

Herr Dr. Martin Scherwinski

Germany

10823

Study participating centre

Herr Alois Schießl

Germany

22041

Study participating centre

Herr Dr. Joachim Schiwietz
Germany
49808

Study participating centre
Herr Dr. Uwe Schläfer
Germany
87439

Study participating centre
Herr Oliver Schlott
Germany
50126

Study participating centre
Herr Heiko Schneider
Germany
99510

Study participating centre
Frau Dr. Stefanie Schrader
Germany
30165

Study participating centre
Frau Dr. Sabine Schulze
Germany
35043

Study participating centre
Herr Toralf Schwarz
Germany
04442

Study participating centre

Herr Dr. Andreas Schwittay

Germany

04564

Study participating centre

Frau Dr. Kathrin Seuß

Germany

95032

Study participating centre

Herr Dr. Andreas Staudenmeyer

Germany

49808

Study participating centre

Herr Dr. Jörg Steindorf

Germany

04435

Study participating centre

Frau Dorothea Stottmeister

Germany

39307

Study participating centre

Herr Dr. Kai Straßmann

Germany

42699

Study participating centre

Frau Dr. EvaMaria Streck

Germany

04643

Study participating centre

Herr Matthias Strickling

Germany

46284

Study participating centre

Frau Dr. Danuta StryjekKaminska

Germany

65185

Study participating centre

Herr Dr. Werner Stürmer

Germany

97080

Study participating centre

Herr Dr. Jörg Tafel

Germany

61350

Study participating centre

Frau Dr. Birgit Teubner

Germany

03046

Study participating centre

Herr Jörg Thelen

Germany

15806

Study participating centre

Frau Svetlana TlechasTkatsch

Germany

14480

Study participating centre

Herr Thomas Voigt

Germany

04654

Study participating centre

Herr Wolf Heinrich von Aufseß

Germany

95445

Study participating centre

Frau Dr. Heike Wagner

Germany

47829

Study participating centre

Frau Ina Walter

Germany

99974

Study participating centre

Frau Dr. Daniela Walther

Germany

67246

Study participating centre

Frau Ingrid Weber

Germany

26725

Study participating centre

Herr Dr. Norbert Wegmann

Germany

52066

Study participating centre

Herr Dr. Rolf Weißmann

Germany

90411

Study participating centre

Herr Dr. Artur Zimmermann

Germany

83043

Study participating centre

Herr Dr. Stefan Zinn

Germany

36341

Study participating centre

Herr Dr. Jens Abendroth

Germany

06188

Sponsor information

Organisation

Sanofi-Aventis Deutschland GmbH

Sponsor details

Potsdamer Str. 8

Berlin

Germany

D-10785

+49 (0)30 2575 2502

Cornelia.Dorn@sanofi.com

Sponsor type

Industry

Website

<https://www.sanofi.de/>

ROR

<https://ror.org/03ytdtb31>

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 51st 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 53rd Annual Meeting of the German Diabetes Association (DDG) at 11.05.2018 in Berlin, Germany. Available at:	11/05/2018		No	No
	Pscherer S, Pfohl M, Fritsche A, Anderten H, Pegelow K, Seufert J. Umstellung des Basalinsulins auf Insulin glargin 0 E/ml (Gla-0) nach				

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 53rd 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