A 12-week randomized, controlled trial to compare TOUJEO® and TRESIBA® in terms of glucose values in target range and variability during continuous glucose monitoring in patients with type 1 diabetes mellitus

Published: 16-10-2019
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To demonstrate the noninferiority of insulin glargine 300 U/mLin comparison to insulin degludec 100 U/mL on glycemiccontrol and variability in participants with diabetes mellitus

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON48426

Source
ToetsingOnline

Brief title
inRange

Condition

- Diabetic complications

Synonym
Diabetes Type I, glucose values

Research involving
Human

Sponsors and support

Primary sponsor: Sanofi-aventis
Source(s) of monetary or material Support: Sanofi

Intervention

Keyword: diabetes type I, Glucose monitoring, LPS14947

Outcome measures

Primary outcome

Percent time in glucose range of *70 to *180 mg/dL (*3.9 to

*10 mmol/L) at Week 12, obtained using continuous glucose

monitoring (CGM)

Secondary outcome

At Week 12, the following endpoints will be assessed:

* Glucose total CV

* Glucose within-day and between-day CV

Other secondary endpoints:

* Change from baseline to Week 12 in HbA1c

* Change from baseline to Week 12 in central lab FPG

* Percent time and mean hours per day with

glucose<70mg/dL (on all time and during the night

[00:00 to 05:59])

* Percent time and mean hours per day with

glucose>180mg/dL

Number of participants with adverse events (see Section 8.3)

Number of participants with at least one hypoglycemic event

from baseline to Week 12

Number of hypoglycemic events per participant year from

baseline to Week 12

Study description

Background summary

The fluctuations in blood glucose, regular short-duration periods of hyperglycemia and hypoglycemia, which are not detected by the measurements of glycated hemoglobin (HbA1c), may possibly contribute to vascular pathological processes and diabetic complications. Insulin glargine U300 (HOE901-U300, Toujeo®) is a more concentrated formulation of insulin glargine U100 (HOE901) which showed a prolonged and flatter glucose-lowering activity (up to 36 hours) compared to Lantus (Insulin glargine U100), resulting in less circadian fluctuation in blood glucose levels (1). Given these features of the pharmacokinetic (PK)/pharmacodynamics (PD) profiles, Toujeo is considered to be well suitable for constant, peakless 24-hour basal insulin supply in diabetes management, with the expectation of less hypoglycemic risk at equal to tighter blood glucose control.

Study objective

To demonstrate the noninferiority of insulin glargine 300 U/mL in comparison to insulin degludec 100 U/mL on glycemic control and variability in participants with diabetes mellitus

Study design

This is a multicenter, randomized, active-controlled, parallel-group, 12-week open-label study to compare the efficacy of Toujeo with Tresiba using 20-day CGM glucose profiles at Week 12. The CGM during study period will be blinded to both the Investigators and patients

Intervention

Patients taking their current basal insulin at any time (eg, evening) other than in the morning should switch their injection time to the morning at randomization.

Study burden and risks

because participants are frequently monitored for blood glucose values, the risk of hyperglycemia and hypogykemie are low.
Participants should be regularly monitored for 12 weeks and need 2x 20 days to wear a continuous glucose meter with them. minimum blood samples can be considered standard of care for this group of participants

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Participants with Type 1 Diabetes mellitus (T1DM)

Participants treated with multiple daily injections (MDI) using basal insulin analog once daily and rapid acting insulin analogs for at least one year

HbA1c * 7% (48 mmol/mol) and * 10% (86 mmol/mol) at screening

Exclusion criteria

Participants not on stable dose of basal insulin analog

Participants having received Toujeo or Tresiba as basal insulin within 30 days prior to screening

Participants not using the same insulins (both basal and rapid) within 30 days prior to screening

Participants having received basal insulin dose *0.6 U/kg body weight within 30 days prior to screening

Participants having received any glucose lowering drugs (including any premixed insulins,human regular insulin as mealtime insulins, any others injectable or oral), other than basal and rapid insulin analogs, within 3 months prior to screening

End stage renal disease or on renal replacement treatment

Retinopathy or maculopathy with one of the following treatments, either recent (within 3 months prior to screening) or planned: intravitreal injections or laser or vitrectomy surgery

Body weight change *5 kg within 3 months prior to screening

Study design

Design

Study phase:	4
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2020
Enrollment:	45
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Toujeo
Generic name:	insulin glargine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Tresiba
Generic name:	insulin degludec
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	16-10-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	11-12-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2017-002756-91-NL
CCMO	NL71287.056.19