A twenty-six week, randomized, open-label, 2-arm parallel group real world pragmatic trial to assess the clinical and health outcomes benefit of transition to Toujeo compared to standard of care insulin, in basal insulin treated patients with uncontrolled type 2 diabetes mellitus, with six month extension.

Published: 23-02-2016
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To demonstrate non-inferiority of Toujeo versus *standard of care* basal insulin therapy asmeasured by HbA1c change from baseline to Month 6.

Ethical review	Not approved
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON43525

Source
ToetsingOnline

Brief title
REGAIN CONTROL

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

1 - A twenty-six week, randomized, open-label, 2-arm parallel group real world pragm ... 13-06-2025

Diabetes Mellitus type 2

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Diabetes Mellitus, open-label, randomized, Toujeo

Outcome measures

Primary outcome

To demonstrate non-inferiority of Toujeo versus *standard of care* basal insulin therapy as measured by glycated hemoglobin (HbA1c) change.

Secondary outcome

-To demonstrate superiority of Toujeo versus *standard of care* basal insulin if non-inferiority criterion is met, measured by HbA1c change.

-To compare Toujeo to other "standard of care" basal insulin in terms of patient persistence with assigned basal insulin therapy with or without intensification

-Risk of hypoglycemia including documented, symptomatic hypoglycemia (*70 mg/dL) or severe (according to ADA Working Group).

-Change in fasting plasma glucose (FPG).

-Change in body weight.

-Differences in patient reported outcomes measured by Diabetes Treatment Satisfaction Questionnaire Status and Change versions (DTSQs and DTSQc).

-Change in hypoglycemic control subscale (HCS).

-Healthcare resource utilization including hospitalizations and emergency

department or other healthcare provider visits and healthcare costs.

Study description

Background summary

The profile of Toujeo compared to Lantus and other *standard of care* basal insulins, combined with a new pen device and an appropriate individualized support, should allow target HbA1c achievement with a lower risk of hypoglycemia. This, in turn, should result in greater patient satisfaction with treatment. A greater number of patients at glycemic goal without hypoglycemia should also lead to decreased resource utilization and associated healthcare costs.
This combination of improved clinical outcomes accompanied by greater patient satisfaction and decreased healthcare costs is of considerable interest to payers globally

Study objective

To demonstrate non-inferiority of Toujeo versus *standard of care* basal insulin therapy as
measured by HbA1c change from baseline to Month 6.

Study design

A phase 4, randomized, open-label, 2-arm parallel group trial.

Intervention

There are two groups:
Group 1: Toujeo 1 time a day by subcutaneous injection.
Group 2: standard of care insulin, 1 or 2 twice a day in the morning and optional in the evening by subcutanious injection.

Study burden and risks

Patients with a poor glycemic control are better followed independent of the type of insulin they use. Because of this a better glycemic control is expected with in return a lowering of hospitalization or health care utilization.

Patients are expected to come to the hospital for 6 visits in total, which

creates also a better awareness for their disease.

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

* Patients with type 2 diabetes insufficiently controlled (HbA1c >7%) with current (* 6 months) *standard of care* basal insulin therapy (including insulin glargine U100, Levemir, NPH or Tresiba) with or without oral agents (metformin, sulfonylurea, thiazolidinedione, DPP-4 inhibitor, SGLT-2 inhibitor, glinides, alpha glucosidase inhibitors) and with or without use of a GLP-1 receptor agonist, ;* Fasting plasma glucose (FPG) >130 mg/dL (7.2 mmol/L), ;* Adult patients who have signed an Informed Consent Form (ICF) and privacy form(s).

Exclusion criteria

* HbA1c *7%, no upper bound,
* Age <18 years,
* Type 1 diabetes mellitus,
* Any clinically significant abnormality identified on physical examination, laboratory tests, or vital signs at the time of screening, or any major systemic disease resulting in short life expectancy that in the opinion of the Investigator would restrict or limit the patient*s successful participation for the duration of the study,
* Use of any product containing short or rapid acting insulin since the time of diagnosis with type 2 diabetes mellitus other than temporary use during a pregnancy or hospitalization,
* Use of any product containing short or rapid acting insulin occurring within 3 months prior to the time of screening,
* Use of oral hypoglycemic agents other than those noted in the inclusion criteria, GLP-1 receptor agonists not approved for use with insulin, or any investigational agent (drug, biologic, device) within 3 months prior to the time of screening.
* All contraindications to *standard of care* insulin therapy or warnings/precautions of use as displayed in the respective National Product labeling for these products.
* Hypersensitivity to insulin glargine or Toujeo excipients
* Pregnancy or lactation,
* Women of childbearing potential with no effective contraceptive method.

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:	Will not start
Enrollment:	20

Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Toujeo
Generic name:	Insulin glargine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-02-2016
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Not approved Date:	07-04-2016
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	EUCTR2015-001832-39-NL
CCMO	NL56445.028.16