A 6-month, multicenter, non-interventional Study to evaluate the Effectiveness and Quality of life impact of the Insulin glargine/Lixisenatide fixed ratio combination in patients with type 2 diabetes mellitus uncontrolled with basal insulin + metformin ± SU: an observational study

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24198

Source
Nationaal Trial Register

Brief title
SEQIL

Health condition

Type 2 Diabetes Mellitus

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Mean change in HbA1c between baseline to study end (week 24)

Secondary outcome

* Mean change in PRO score from baseline to week 12 and from baseline to study end (week 24);
 WHO-5 - emotional well-being (5 items)
 IWQOL-LITE – Impact of weight on quality of life (5 domains, 31 items)
 SDSCA – 1 item medication-adherence
 DMSRQ – treatment satisfaction/convenience
* Mean change in HbA1c between baseline and week 12;
* The percentage of patients reaching HbA1c <7% after 24 weeks;
* Mean change in body weight and BMI between baseline and week 12 and week 24;

Study description

Background summary

To evaluate the effectiveness of IGlarLixi in improving glycemic control and to assess change in patient well-being (PRO) after switch to IGlarLixi in T2DM patients inadequately controlled with basal insulin + metformin ± SU. This objective is being studied in a real-world setting, where patients are observed for 24 weeks after having been switched from basal insuline to IGlarLixi.

Study objective

Based on evidence to date, we can assume glycemic and weight benefits from IGlar combined with short-acting GLP-1 RA lixisenatide in T2DM in suboptimal glycemic control, but real-world evidence is needed. Moreover, whether these benefits translate into improved patient-reported outcomes (PRO's) has yet to be established. In this context patients' expectations and perceived convenience, weight-related QoL, hypoglycemia concerns and gastrointestinal side-effects are of particular interest.

Study design

Baseline, week 12, week 24

Intervention

No therapeutic interventions. Patients are asked to complete PROs at three different time points (baseline, Month 3, Month 6).

Contacts

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Eligibility criteria

Inclusion criteria

* T2DM patients on basal insulin for at least 3 months + metformin ± sulfonylureas;
* For which the Investigator has decided to prescribe IGlarLixi independently from entry in the study (within 1 week of study entry);
* BMI ≥ 30 kg/m2
* ≥ 18 years of age

Exclusion criteria

* Diagnosis for T1DM;
* Use of mealtime insulin or premix insulin within 6 months before switching to IGlarlixi;
* Current use of GLP-1 RA;
* Hypersensitivity to IGlarLixi or any of its components;
* Pregnant (or intention to become pregnant during the course of the registry) or breast-feeding woman;
* Incapability to fill in PRO questionnaires (at the discretion of the investigator)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2020
Enrollment:	107
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL7648
Other	MEC-U : NWMO19.04.016

Study results