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Non-interventional study with Suliqua® (30-60) pen in daily practice in patients with type 2 diabetes

Submission date
07/02/2024

Recruitment status
No longer recruiting

Registration date
28/05/2024

Overall study status
Completed

Last Edited
10/06/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
This is an observational study that is being conducted to obtain information about the treatment with Suliqua® (insulin glargine/lixisenatide (iGlarLixi)) in patients with type 2 diabetes mellitus in daily practice. In this type of study (observational study) your treatment is based on the decision made by you together with your treating physician. This observational study will not determine or change your treatment in any way. If you decide to participate, information about you, your condition and the course of treatment of your type 2 diabetes mellitus type 2 will be collected. Suliqua® is used as an adjunct to diet and exercise in addition to metformin with or without SGLT-2 inhibitors for the treatment of adult patients with inadequately controlled type 2 diabetes mellitus to improve glycaemic control. The aim of this non-interventional study is to evaluate the efficacy and safety of iGlarLixi in patients with type 2 diabetes in a clinical setting patients with type 2 diabetes who, due to inadequate glycaemic control on basal insulin in combination with control on basal insulin in combination with oral antidiabetic drugs (OADs) by their doctor switched to Suliqua® by their doctor.

Who can participate?
Adult patients with type 2 diabetes mellitus in treatment with OADs.

What does the study involve?
The course of treatment of all participating patients will be monitored for a maximum of 6 months after the start of treatment with Suliqua®.

What are the possible benefits and risks of participating?
You are helping us by participating, gain more knowledge about the treatment of type 2 diabetes mellitus patients with Suliqua®, e.g. the use and tolerability of Suliqua® in everyday practice. These findings may help to further improve the treatment of type 2 diabetes mellitus patients in the future.

Where is the study run from?
Sanofi-Aventis GmbH Germany

When is the study starting and how long is it expected to run for?
November 2019 to August 2022

Who is funding the study?
Sanofi-Aventis GmbH Germany

Who is the main contact?
Dr Katrin Pegelow, katrin.pegelow@sanofi.com
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Additional identifiers

Protocol serial number
OBS16751

Study information

Scientific Title

A prospective observational study to assess glycaemic control by intensifying therapy with iGlarLixi in the Suliqua® (30-60) pen in daily practice in patients with type 2 diabetes whose blood sugar is not adequately controlled on basal insulin and oral antidiabetic therapy

Acronym
CHANCE NiS

Study objectives
CHANCE provides specific insights on people with type 2 diabetes (T2D) insufficiently controlled on at least 30 units per day of basal insulin in a basal insulin and oral antidiabetic therapy (BOT) regimen, who are switched to 30 dose steps per day iGlarLixi.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/08/2020, Saxon State Medical Association (Schützenhöhe 16, Dresden, 01099, Germany; +49 (0)3518267307; ethik@slaek.de), ref: EK-BR-98/20-1

Primary study design
Observational

Study design
Prospective multicentre non-interventional study

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Site and patient selection:
This non-interventional study (NIS) was conducted in accordance with Good Pharmacoepidemiology Practice (GPP) guidelines and in accordance with local legal and ethical guidelines. It was distributed by employees of Sanofi (Germany) and conducted with general practitioners, diabetologists or in practices or outpatient clinics with a focus on diabetology. The participating physicians were familiar with the software of the flash glucose monitoring (FGM) systems and already used them in their daily practice to evaluate the FGM data.

Study sites were selected by Sanofi-Aventis Deutschland GmbH and supervised by a CRO (AKP GmbH).

Type 2 diabetes patients were included for whom the treating physician had made the decision to switch the basal insulin to iGlarLixi based on the iGlarLixi SmPC independent of the context of the NIS and independent of the patient’s inclusion into the NIS. The patients had to be experienced with the use of their self-monitoring blood glucose (SMBG) or FGM device and should not plan to change their device during the study.

Data and safety data collection:
There was no fixed scheme for the documentation of data. The visits were based on clinical practice with data collection at Week 0, and approx. 4, 8, 12, 16, 20, and 24 weeks after switching to iGlarLixi. No deviation longer than ± 3 weeks from the specified times was recommended. Data were collected via eCRF (electronic documentation form). The electronic data processing system could lead to additional clarifying questions that the participating physician was obligated to answer by confirming or modifying the data concerned.

Data collection and validation procedures were processed in detail in appropriate operating documentation, such as the data management plan (DMP) and data validation plan (DVP).

All adverse events (AEs), serious adverse events (SAEs), adverse drug reactions (ADRs), adverse drug effects (ADEs), adverse events of special interest (AESIs) and other safety-relevant events (overdose, misuse, abuse, occupational exposure, pregnancy, incidents with medical devices, medication errors, applications outside of the licensed approval, hypersensitivity reactions), regardless of their causal connection with iGlarLixi, from the time of signing the informed consent form until the end of the study (as defined for each patient in the observation plan), had to be documented on the relevant page(s) of the eCRFs. SAEs had to be documented immediately (within one working day after becoming known), and non-serious AEs had to be documented within 30 calendar days. A backup plan was to be used (i.e., using hard copies) in case the eCRF system failed.

Reporting procedures for AEs and other safety-relevant events were predefined in the observational plan (Appendix 3.1) with respect to input, transmission, and additional data updates to be sent to AKP. This was also due to the reporting of suspected quality defects (PTC: Product Technical Complaints).

Data management, review, validation:
The processes of data collection and validation are described in detail in appropriate operational documents, such as the data management plan (DMP) and data validation plan (DVP). Data quality control (site monitoring and/or phone QC) was performed at site level, in 5% of the participating sites (which had documented at least one patient), chosen at random. The treating physician consented by signing the contract to make all information available to the sponsor for the purpose of verification.

Statistical considerations:
It was planned to document 250 patients at 100 sites in Germany.

An interim analysis was planned after approx. 12 weeks or 50 patients, however, no interim analysis was performed.

Intervention Type
Other

Primary outcome(s)
Documentation of the absolute change in HbA1c (%) from switching to iGlarLixi (fixed ratio combination [FRC] of insulin glargine 100 U/mL and 33 µg/mL lixisenatide) treatment from an existing BOT in everyday clinical practice until approx. 12 and approx. 24 weeks, respectively, after start of iGlarLixi treatment.

Key secondary outcome(s)

Documentation of the changes in other glycaemic parameters, during approx. 12 and approx. 24 weeks of treatment with iGlarLixi, respectively, and documentation of the tolerability of iGlarLixi in everyday clinical practice.

The following secondary endpoints were evaluated:
1. Relative change in HbA1c (%)
2. Absolute and relative change in self-measured fasting blood glucose (FBG) (mg/dL)
3. Proportion of patients achieving their individualised HbA1c target (%)
4. Proportion of patients achieving FBG ≤110 mg/dL [≤6.1 mmol/L] (%)
5. Absolute and relative change in 7-point blood glucose daily profile (mg/dL)
6. Last dose of previous basal insulin (units/day [U/d])
7. Absolute and relative change in iGlarLixi dose (dose steps/day [DS/d])
8. Absolute and relative change in body weight (kg)
9. Absolute change in BMI (kg/m²)
10. Absolute and relative change in glucose measured at median (mg/dL)
11. Absolute and relative change in SD of glucose profiles (mg/dL)
12. Incidence and rate of hypoglycaemic episodes3 (documented hypoglycaemic episodes within the last approx. 12 weeks prior to study inclusion compared to the last 12 weeks prior to documentation 2 [after approx. 12 weeks] and the last 12 weeks prior to the final documentation [after approx. 24 weeks])
13. Change in treatment satisfaction using DTSQs and DTSQc

Completion date
04/08/2022

Eligibility

Key inclusion criteria
1. Adult patients with type 2 diabetes mellitus
2. In treatment with OADs and a basal insulin without predialysis insulin and without GLP1-RA for at least 6 months
3. HbA1c 7.5% to 10.0% (findings from the last 3 months)
4. Presence of prior basal insulin therapy that is stable between 30-60 units per day
5. Switching to iGlarLixi takes place between 14 days before the initial documentation and 7 days after the initial documentation
6. Decision of the treating physician to replace the previous basal insulin with iGlarLixi regardless of the enrolment in the study
7. Ability and willingness to perform 7-point glucose daily profile measurements using a glucometer OR self-management using an FGM system. FGM patients should only be included if:
7.1. At least 70% of recorded sensor data from the FGM daily profiles of the last approx. 14 days (max. 3 weeks) are available before switching to iGlarLixi
7.2. No change of the FGM system manufacturer used during the study period is planned; however, a switch to a device of the same manufacturer (e.g. the latest device generation) is possible
7.3. Calibration of the FGM system is guaranteed according to the manufacturer’s specifications
8. Informed consent signed by the patient and physician

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
92

Key exclusion criteria
1. Type 1 diabetes mellitus
2. Contraindications to treatment with iGlarLixi according to the Summary of Product Characteristics
3. Participation in clinical research
4. Planned or existing pregnancy, cancer, drug or alcohol abuse, dementia, or general inability to understand the content of the observational study
5. Daily basal insulin dose <30 units or >60 units

Date of first enrolment
24/09/2020

Date of final enrolment
17/01/2022

Locations

Countries of recruitment
Germany

Study participating centre
Tobias Wiesner
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Sponsor information

Organisation
Sanofi (Germany)

ROR
https://ror.org/03ytdtb31

Funder(s)

Funder type
Industry

Funder Name
Sanofi-Aventis Deutschland

Alternative Name(s)
Sanofi, Sanofi in Deutschland, Sanofi-Aventis Deutschland GmbH

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
Data available on request due to privacy/ethical restrictions. The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/01/2025	10/06/2025	Yes	No
Funder report results	version 1.0	04/08/2023	23/02/2024	No	No