Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The assessment of the safety and efficacy of Basalin (Insulin glargine) in patients with type 2 diabetes: a postmarketing survey

Protocol summary

Study aim
Assessment of the safety and efficacy of Basalin® insulin glargine in type 2 diabetic patients

Design
A post-marketing-survey of phase 4 on 400 type 2 diabetic patients.

Settings and conduct
This prospective postmarketing study will be performed on 400 type 2 diabetic patients referred to endocrine and metabolism research centers. After qualifying for inclusion in the study, the study protocol will be explained to the patient. After obtaining informed consent, each patient will be followed up for 6 months from the start of insulin or until the day of discontinuation of the drug if necessary. Patient information such as demographics, medications, and vital signs are entered in the CRF form. Then, Basalin insulin glargine, which is in the form of 100 U / ml pens and is injected subcutaneously, will prescribed to patients by an endocrinologist. How to start and adjust the dose of Basalin will be based on the ADA 2020 protocol. Each patient is given a glucometer to measure blood sugar and is taught how to measure blood glucose. A booklet is also delivered to the patient to record the amount of blood glucose and brings in each visit At each visit, the patient is examined for any drug-related side effects. If necessary, the dose of medication will be adjusted by the treating physician.

Participants/Inclusion and exclusion criteria
Type 2 diabetic patients of both sexes who have been treated with oral hypoglycemic drugs for at least 6 months prior to the study and have not achieved their diabetes control goals. Also, patients have not received long-acting insulins in the last 6 months.

Intervention groups
After being eligible for the study participation and obtaining informed consent, all patients will be treated with subcutaneously insulin glargine Basalin for 6 months.

Main outcome variables
-Changes in glycated hemoglobin -Changes in blood glucose

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201230049882N1**
Registration date: **2021-02-23, 1399/12/05**
Registration timing: **prospective**

Last update: **2021-02-23, 1399/12/05**
Update count: **0**

Registration date
2021-02-23, 1399/12/05

Registrant information

Name
Mohammadreza Mohajeri-Tehrani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8822 0037

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mrmohajeri@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2022-04-21, 1401/02/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of the safety and efficacy of Basalin (Insulin glargine) in patients with type 2 diabetes: a postmarketing survey

Public title

Assessment of efficacy of Basalin (Insulin glargine) in type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetic patients of both sexes and between 30-65 years of age. Patients who have been treated with oral glucose medications for at least 6 months prior to the start of the study and have not achieved their therapeutic goals (7.5%<HbA1C<9.5%) and not achieving the goals of glucose control with at least two oral antihyperglycemic agents with maximum tolerated dose Patients who have not received Lantus insulin glargine or any long-acting insulin in the last 6 months. Body mass index < 35 kg/m2 Glomerular filtration rate more than 30 ml/min. Following a caring diet and exercise regimen recommended by the medical team and tend to maintain them for the entire duration of the study.

Exclusion criteria:

History of diabetic ketoacidosis before the study Hospital admission history more than 2 times due to diabetes in the last 1 year History of brittle diabetes (a condition in which the disease is very difficult to control, as the patient's blood sugar level fluctuates from very low to very high) The presence of any severe complications of diabetes, including end-stage renal disease, advanced coronary artery disease or myocardial infarction during the 6 months prior to the study, or autonomic peristaltic problems, such as gastroparesis. Laboratory disorders at the beginning of the study, such as high levels of liver enzymes more than 3 times above normal limit History of cirrhosis (CHILD C) Uncontrolled thyroid disease History of autoimmune diseases Treatment with glucocorticoids, immunosuppressive or cytotoxic drugs for 60 days prior to enrollment Presence of any active malignancy or history of malignancy History of drug or alcohol abuse (based on patient self-expression) Severe physical and mental disorders Pregnancy, breastfeeding or planning to get pregnant in the next 6 months Simultaneous participation of the patient in another clinical trial or taking any other study drug from 6 months before enrollment History of positive test results for HIV, hepatitis B or hepatitis C, or covid-19 History of organ transplantation

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **400**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Endocrine and metabolism research institute - Tehran university of medical sciences

Street address

Next to Dr. Shariati Hospital, Jalal Al-Ahmad Highway

City

Tehran

Province

Tehran

Postal code

1411713137

Approval date

2021-01-11, 1399/10/22

Ethics committee reference number

IR.TUMS.EMRI.REC.1399.066

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E10, E11

ICD-10 code description

Type 1 diabetes mellitus, Type 2 diabetes mellitus

Primary outcomes

1

Description

HbA1c changes

Timepoint

At the beginning of the study, week 12 and week 24

Method of measurement

Chromatography

2

Description
Blood glucose changes
Timepoint
At the beginning, week12 , and week 24
Method of measurement
Enzymatic method

Secondary outcomes

1

Description
Percentage of patients who achieve their blood sugar control goals.
Timepoint
End of week 24 after starting the study
Method of measurement
Measuring Glycated hemoglobin using chromatography method

Intervention groups

1

Description
Intervention group: Insulin glargine Basalin, which is in 100 U / ml pens and is injected subcutaneously, will be prescribed to patients by an endocrinologist. The adjustment of drug dose will be based on the American Diabetes Association 2020 protocol.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology and metabolism research center
Full name of responsible person
Mohammadreza Mohajeri-Tehrani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Pooyesh darou
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Pooyesh darou
Full name of responsible person
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact
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endocrinology and metabolism institute, Tehran university of medical sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable