

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 be 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)

Phone

+98 21 8822 0037

Email address

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 ($7.5\% < \text{HbA1C} < 9.5\%$) 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 $< 35 \text{ kg/m}^2$ 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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Shariati hospital, North Karegar Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pooyesh darou

Full name of responsible person

Dr. Sina Ebrahimi

Street address

NO. 13, 5th Ave, Fatemi St, Tehran, Iran

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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

Dr. Sina Ebrahimi

Position

Medical Manager

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

endocrinology and metabolism research institute,
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Full name of responsible person

Mohammadreza Mohajeri-Tehrani

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinology and metabolism

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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medical doctor- researcher

Latest degree

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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