Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A randomized, two-armed, parallel, double-blind, active-controlled, non-inferiority clinical trial to compare efficacy and safety of test-liraglutide (CinnaGen Co., Iran) to innovator liraglutide product (Victoza®, Novo Nordisk, Denmark) in patients with type II diabetes (T2D)

Protocol summary

Study aim

Comparing the efficacy and safety of Cinnagen liraglutide and Novo Nordisk Victoza® in type II diabetes patients

Design

randomized, two-armed, parallel, double-blind, active-controlled, non-inferiority clinical trial of 300 type II diabetes patients

Settings and conduct

2 cities (Tehran and Karaj) and 17centers will participate in this study. The patients will be included in the study after declaring informed consent and meeting specific inclusion/exclusion criteria. Initially, the patients will be given a randomization code and will be allocated randomly to one of the two intervention groups. The study drugs will be used in exact identical shape, box, and labels so the investigator, the patient, and data analyzer will be completely unaware of the drug which certain patient has received. Subsequently, the patient will be injected daily and Evaluation and clinical examination will be performed in 7 visits and will be monitored for 6 months after the first injection.

Participants/Inclusion and exclusion criteria

Subjects with type 2 diabetes treated for ≥3 months with a stable metformin dose of ≥1500mg and at least half the maximum dose of a insulin secretagogues agent; 18–80years old; 7≤HbA1c≤10.5; BMI:20-45 Kg/m2 and informed consent; no Hypersensitivity to liraglutide or any formulation component, no Insulin treatment during the previous 3 months; Impaired liver or renal function:Uncontrolled hypertension; Malignancy; History or family history of Medullary Thyroid Carcinoma or MEN syndrome type 2; History of pancreatic cancer and pancreatitis; Recent MI; Pregnancy or Previous exposure to exenatide or liraglutide.

Intervention groups

either liraglutide (cinnagen) or victoza group receive 0.6 mg/day subcutaneous liraglutide for a week and then 1.2 mg/day up to 3 weeks and finally 1.8 mg/day to the end of week 26

Main outcome variables

Change in HbA1c after 26 weeks of treatment

General information

Reason for update

Protocol changes:Blood test and antidrug antibody presence evaluating (week 0 week 12 and week 26) HbA1c equal or greater than 7 and equal or smaller than 10.5 18–80years of age Subjects with type 2 diabetes treated for ≥ 3 months with a stable metformin dose of ≥1500 mg and at least half the maximum dose of a sulfonylurea or non-sulfonylurea insulin secretagogues agent(Half of maximum dose) breast-feeding Female who intends to become pregnant during the clinical trial period Dr. Mahsan Seifoddin-Melli Bank Hospital Dr. Mohammad Khaledi- Lolagar Hospital

Acronym

IRCT registration information

IRCT registration number: **IRCT20150303021315N15**
Registration date: **2019-09-13, 1398/06/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-29, 1399/07/08**
Update count: **3**

Registration date

2019-09-13, 1398/06/22

Registrant information

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Orchid Pharmed

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-10, 1398/03/20

Expected recruitment end date

2021-05-02, 1400/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized, two-armed, parallel, double-blind, active-controlled, non-inferiority clinical trial to compare efficacy and safety of test-liraglutide (CinnaGen Co., Iran) to innovator liraglutide product (Victoza®, Novo Nordisk, Denmark) in patients with type II diabetes (T2D)

Public title

Comparing Efficacy and Safety of CinnaGen-liraglutide Versus Victoza® in Patients with Type II Diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Subjects with type 2 diabetes treated for ≥ 3 months with a stable metformin dose of ≥1500 mg and at least half the maximum dose of a sulfonylurea or non-sulfonylurea insulin secretagogues agent(Half of maximum dose) 18–80years of age HbA1c equal or greater than 7 and equal or smaller than 10.5 Body mass index (BMI) of 20-45 kg/m2

Exclusion criteria:

Lack of consent for being in the trial and not complying with 26-weeks follow-up period Hypersensitivity to liraglutide or any component of the formulation (excipients include Disodium phosphate dehydrate, Propylene glycol, Phenol, Water for injection) Insulin treatment during the previous 3 months (except short-term treatment for intercurrent illness) Impaired liver function (alanine aminotransferase concentrations equal to or greater than 2.5 times upper normal range). Impaired renal function (eGFR smaller than 60 mL/min/1.73 m2) Uncontrolled hypertension (equal or greater than 160/100 mmHg) Malignancy Using any drugs apart from OGLAs likely to affect glucose concentrations, including androgens, hyperglycemia-associated agents, hypoglycemia-associated agents, MAO inhibitors, quinolone antibiotics, salicylates (Anti-inflammatory dose). Current use of a dipeptidyl peptidase-4 inhibitor (DPP-4i) Treatment with systemic corticosteroids within last three months History or family history of Medullary Thyroid Carcinoma (MTC) Multiple endocrine neoplasia syndrome type 2 (MEN2) History of pancreatic cancer and pancreatitis History of recent MI, uncontrolled CHF, and unstable Angina within last 3 months History or known case of severe non-proliferative diabetic retinopathy or proliferative diabetic retinopathy Pregnancy or breast-feeding Female who intends to become pregnant during the clinical trial period Previous exposure to exenatide or liraglutide.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization plan of the patients will be carried out centrally using an R-CRAN software version 3.2.3. Blocks (with the size 2 or 4) will be made using permuted block randomization for a total of 300 patients (1:1 allocation ratio). After randomization procedure, a code will be allocated to each patient that will be used as patient identifier throughout the study. The assigned code will be denoted by 4 initials (corresponding to the first two letters of first name, first two letters of surname) and 4 numbers (center code). Moreover, the described code is followed by study unique identification code consisting of first two letters of the generic name of the investigational product and study phase number, respectively (LI3), and four numbers (corresponding to the randomization number), e.g. ABCD0001LI3-0001. The randomization number will be assigned in a consecutive way.

Blinding (investigator's opinion)

Double blinded

Blinding description

The medication compartment of both Victoza® and test-liraglutide (CinnaGen) will be placed in similar pen-injector containers, in a way that they cannot be differentiated by the appearance. Additionally, The center researcher and the patient are not aware of the drug grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name
ClinicalTrial.gov
Secondary trial Id
NCT03421119
Registration date
2018-02-02, 1396/11/13

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
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Near Milad Tower, Shahid Hemmat Highway
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Approval date
2019-01-23, 1397/11/03
Ethics committee reference number
IR.IUMS.REC.1396.31731

2

Ethics committee
Name of ethics committee
Ethics Committee of Alborz University of Medical Sciences
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Approval date
2019-06-15, 1398/03/25
Ethics committee reference number
IR.ABZUMS.REC.1398.052

Health conditions studied

1

Description of health condition studied
type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Change in HbA1c after 26 weeks of treatment
Timepoint
Screening, baseline, week 12, and week 26
Method of measurement
By High-performance liquid chromatography (HPLC)

Secondary outcomes

1

Description
Percentages of subjects achieving HbA1c < 7.0%
Timepoint
Screening, baseline, week 12, and week 26
Method of measurement
-By High-performance liquid chromatography(HPLC)

2

Description
Percentages of subjects achieving HbA1c ≤ 6.5%
Timepoint
Screening, baseline week 12, and week 26
Method of measurement
By High-performance liquid chromatography(HPLC)

3

Description
Changes in body weight
Timepoint
Screening, baseline week 12, and week 26
Method of measurement
Scales

4

Description
Changes in mean FBS
Timepoint
Baseline, week 12, and week 26
Method of measurement
Laboratory Test

5

Description
Changes in mean PPBS
Timepoint
Baseline, week 12, and week 26
Method of measurement
Laboratory Test

6

Description
Changes in Systolic Blood Pressure
Timepoint

Screening, baseline, week 4, week 8, week 12, and week 26

Method of measurement

Medical examination

7

Description

Changes in Diastolic Blood Pressure

Timepoint

Screening, baseline, week 4, week 8, week 12, and week 26

Method of measurement

Medical examination

8

Description

Changes in Lipid profiles

Timepoint

Baseline, week 12, and week 26

Method of measurement

Laboratory Test

9

Description

Change in Pulse Rate

Timepoint

Screening, baseline, week 4, week 8, week 12, and week 26

Method of measurement

Medical examination

10

Description

Change in eGFR

Timepoint

Screening, baseline, week 12, and week 26

Method of measurement

Laboratory Test

11

Description

Change in ALT

Timepoint

Screening, Baseline, week 12, and week 26

Method of measurement

Laboratory Test

12

Description

Change in liver AST

Timepoint

Baseline, week 12, and week 26

Method of measurement

Laboratory Test

13

Description

Adverse events with special focus on the incidence, severity, and duration of gastrointestinal disturbances, nausea, vomiting, diarrhea; kidney function (BUN, SCr), liver function (ALT, AST, ALP), serum levels of Amylase and Lipase, tachycardia/palpitation, and antibody formation

Timepoint

Screening, baseline, week 4, week 8, week 12, week 16, week 20, and week 26

Method of measurement

evaluation adverse events and adverse drug reaction

14

Description

Change in quality of life

Timepoint

Baseline, week 12 and week 26

Method of measurement

EQ5D questionnaire

15

Description

Medication adherence

Timepoint

Baseline, week 12 and week 26

Method of measurement

Morisky questionnaire

16

Description

Cost-effectiveness

Timepoint

Baseline, week 4, week 8, week 12, week 16, week 20 and week 26

Method of measurement

Cost-effectiveness questionnaire

17

Description

Fear of injection

Timepoint

Baseline, week 12 and week 26

Method of measurement

D-FISQ questionnaire

Intervention groups

1

Description

Liraglutide (produced by CinnaGen Co.) pen-injector (18 mg/3 ml), subcutaneous injection of 0.6 mg every day for one week, followed by a dose of 1.2 mg per day for up to three weeks. Then, 1.8 mg daily subcutaneous injection will be performed until the end of week 26.

Category

Treatment - Drugs

2

Description
Victoza® (produced by Novo Nordisk Company) pen-injector (18 mg/3 ml), subcutaneous injection of 0.6 mg every day for one week, followed by a dose of 1.2 mg per day for up to three weeks. Then, 1.8 mg daily subcutaneous injection will be performed until the end of week 26.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Institute of Endocrinology and Metabolism Research andTraining Center

Full name of responsible person
Mohammad Ebrahim Khamseh

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Recruitment center

Name of recruitment center
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Recruitment center

Name of recruitment center
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4

Recruitment center

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Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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CinnaGen Company
Full name of responsible person
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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
CinnaGen Company
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
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available