Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the effectiveness and safety of Spartina® (Tirzepatide manufactured by CinnaGen) in patients with prediabetes and overweight or obesity

Protocol summary

Study aim
The objectives of this study are to assess effectiveness, and safety of Spartina®

Design
Before-after, single-armed, prospective study

Settings and conduct
A post-marketing real-world study for evaluating effectiveness and safety of Spartina® (Tirzepatide manufactured by CinnaGen Co.) in patients with prediabetes and obesity or overweight with weekly injection

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1.Male or female ≥18 years of age 2.BMI ≥ 27 or WC ≥ 94 cm (Men) / ≥ 80 cm (Women). 3.Willingness for signing and having signed the informed consent form 4.Confirmed prediabetes diagnosis (100 ≤ FBS ≤ 125 OR 5.6 ≤ HbA1C ≤ 6.4 OR 140 ≤ 2hPP ≤ 199) Exclusion criteria: 1.Prior use of any GLP-1 agonist in the last 6 months 2.Any condition or circumstance that might pose a risk to the subject or interfere with the ability to acquire satisfactory clinical data (e.g. acute pancreatitis/suspicious for pancreatitis, acute cholecystic disorders, severe hypoglycemia, hypersensitivity to the drug class, severe or sustain gastroenteric adverse events (grade3 or higher)) 3.Pregnancy or breast-feeding 4.Personal or family history of MTC or patients with MEN 2 syndrome 5.Diabetes diagnosis

Intervention groups
Tirzepatide (2.5–7.5 mg once weekly), dose should be increased to 5 mg after the first month in case of good tolerability

Main outcome variables
Waist circumference (WC) Body mass index (BMI) Weight Blood pressure FBS HbA1C HOMA-IR ASCVD

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150303021315N42**
Registration date: **2026-05-20, 1405/02/30**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-20, 1405/02/30**
Update count: **0**

Registration date
2026-05-20, 1405/02/30

Registrant information

Name
Nassim Anjidani

Name of organization / entity
Orchid Pharmed

Country
Iran (Islamic Republic of)

Phone
+98 21 4347 3000

Email address
amini@orchidpharmed.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-04-21, 1405/02/01

Expected recruitment end date
2026-05-22, 1405/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluating the effectiveness and safety of Spartina® (Tirzepatide manufactured by CinnaGen) in patients with prediabetes and overweight or obesity

Public title
Before-after study of Spartina® (CinnaGen Co.)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Male or female ≥18 years of age Body mass index (BMI) ≥ 27 or waist circumference (WC) ≥ 94 cm (Men) / ≥ 80 cm (Women). Willingness for signing and having signed the informed consent form Confirmed prediabetes diagnosis (100 ≤ Fasting blood sugar (FBS) ≤ 125 OR 5.6 ≤ HbA1C ≤ 6.4 OR 140 ≤ 2-hours post prandial glucose ≤ 199)

Exclusion criteria:
Prior use of any glucagon-like peptide-1 (GLP -1) agonist in the last 6 months Any condition or circumstance that might pose a risk to the subject or interfere with the ability to acquire satisfactory clinical data (e.g. acute pancreatitis/suspicious for pancreatitis, acute cholecystic disorders, severe hypoglycemia, hypersensitivity to the drug class, severe or sustain gastroenteric adverse events)grade 3 or higher)) Pregnancy or breast-feeding Personal or family history of medullary thyroid carcinoma (MTC) or patients with multiple endocrine neoplasia syndrome type 2 (MEN 2) Diabetes diagnosis

Age
From **18 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Tehran, Chamran Highway, Evin, next to Taleghani Hospital, Building No. 2, Deputy of Research and Technology

City
Tehran

Province
Tehran

Postal code
۱۹۸۳۹۶۹۴۱۱

Approval date
2026-04-18, 1405/01/29

Ethics committee reference number
IR.SBMU.NNFTRI.REC.1405.014

Health conditions studied

1

Description of health condition studied
Prediabetes and overweight or obesity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Mean of fasting blood sugar (FBS) at day 90

Timepoint
Day 90

Method of measurement
Laboratory test

Secondary outcomes

1

Description
Mean change from baseline in FBS at day 90

Timepoint
Day 0, Day 90

Method of measurement
Laboratory test

2

Description
Proportion of patients with equal to or more than 5% weight loss at day 90

Timepoint
Day 0, Day 90

Method of measurement
Weighting with scale

3

Description
Percent change in body weight from baseline till day 90
Timepoint
Day 0, Day 90
Method of measurement
Weighting with scale

4

Description
Absolute change in body weight from baseline till day 90
Timepoint
Day 0, Day 90
Method of measurement
Weighting with scale

5

Description
Mean change from baseline in body mass index (BMI) at day 90
Timepoint
Day 0, Day 90
Method of measurement
Division of weight by square of height

6

Description
Mean change from baseline in waist circumference (WC) at day 90
Timepoint
Day 0, Day 90
Method of measurement
Measurement by tape

7

Description
Mean change from baseline in systolic blood pressure at day 90
Timepoint
Day 0, Day 90
Method of measurement
Using Sphygmomanometer

8

Description
Mean change from baseline in diastolic blood pressure at day 90
Timepoint
Day 0, Day 90
Method of measurement
Using Sphygmomanometer

9

Description
Proportion of patients achieving normoglycemia at day 90
Timepoint
Day 90
Method of measurement
Lab oratory test

10

Description
Mean change from baseline in HbA1C at day 90
Timepoint
Day 0, Day 90
Method of measurement
Lab oratory test

11

Description
Mean change from baseline in homeostatic model assessment for insulin resistance (HOMA-IR) index at day 90
Timepoint
Day 0, Day 90
Method of measurement
Using HOMA-IR formula

12

Description
Mean change from baseline in 10-years atherosclerotic cardiovascular disease (ASCVD) risk at day 90
Timepoint
Day 0, Day 90
Method of measurement
Using 10-years ASCVD formula

Intervention groups

1

Description
Intervention group: Tirzepatide (2.5–7.5 mg once weekly), dose should be increased to 5 mg after the first month in case of good tolerability
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti University
Full name of responsible person
Dr. Jalaledin Mirzay Razaz
Street address
Tehran, Quds town (the West) Shahid Farahzadi Boulevard, Shahid Hafezi Street (Western purple) Plaque 7
City
Tehran
Province
Tehran

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1981619573
Phone
+98 21 2235 7483
Email
Jmrazaz@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
CinnaGen Company
Full name of responsible person
Mehran Montajabi Niyat
Street address
Simin Dasht Industrial Park, Karaj, Alborz, Iran
City
Karaj
Province
Tehran
Postal code
3165933155
Phone
+98 26 3667 0334
Email
info@cinnagen.com
Web page address
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
Name of organization / entity
Orchid Pharmed Co.
Full name of responsible person
Dr. Hamidreza Kafi
Position
Medical Department Manager
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Jalaledin Mirzay Razaz
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Tehran, Quds town (the West) Shahid Farahzadi Boulevard, Shahid Hafezi Street (Western purple) Plaque 7
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Jmrazaz@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Orchid Pharmed Co
Full name of responsible person
Dr. Hamid reza Kafi
Position
Medical Department Mnager
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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No 42. Attar sq, Attar st, Valiasr st,Vanak sq, Tehram, Iran
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Kafi.H@orchidpharmed.com

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

Not applicable

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

Not applicable