Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the effectiveness and safety of Spartina® (Tirzepatide manufactured by CinnaGen Co.) in patients with obesity and type 1 diabetes

Protocol summary

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

Design
Before-after, single-armed, prospective, real-world, non-randomized study in 38 patients

Settings and conduct
Eligible individuals presenting to the determined centers will enter the run-in period and will undergo CGM for one month. At the end of this period, they will be enrolled in the study if they meet all eligibility criteria upon final assessment. Spartina® will be administered once weekly throughout the three-month study period. During the first month, the weekly dose will be 2.5 mg. If the medication is well tolerated, after one month the dose should be increased to 5 mg. In the third month, the dose may be increased to 7.5 mg at the physician's discretion. Data will be collected throughout the treatment period and will undergo analysis and the results will be reported.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1. Male or female between 18-60 years with at least 1-year history of type -1 diabetes and BMI ≥ 27 2. Willingness to consent Exclusion criteria: 1. Use of any GLP-1 agonist or SGLT2 inhibitors or corticosteroids in the last 6 weeks 2. History of diabetic ketoacidosis, severe hypoglycemia, unstable coronary events or stroke in the last 3 months 3. History of bariatric surgery 4. Any condition that might pose a risk to the subject 5. Pregnancy or breast-feeding 6. History of proliferative diabetic retinopathy or macular edema. 7. Personal or family history of MTC or patients with MEN-2 syndrome

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
WC, BMI, Weight, FBS, HbA1C, Glycemic variability, Insulin dose, Time of blood glucose in or out of range

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150303021315N47**
Registration date: **2026-10-29, 1405/08/07**
Registration timing: **prospective**

Last update: **2026-10-29, 1405/08/07**
Update count: **0**

Registration date
2026-10-29, 1405/08/07

Registrant information

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Nassim Anjidani

Name of organization / entity
Orchid Pharmed

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-31, 1405/08/09

Expected recruitment end date
2027-04-29, 1406/02/09

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 Co.) in patients with obesity and type 1 diabetes

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female between 18-60 years of age (inclusive) with at least 1-year history of type -1 diabetes BMI ≥ 27 Ability to comprehend and willingness to give consent for this study

Exclusion criteria:

Prior use of any GLP-1 agonist or SGLT2 inhibitors or corticosteroids in the last 6 weeks History of diabetic ketoacidosis, severe hypoglycemia, unstable coronary events or stroke in the last 3 months History of previous weight loss surgery Any condition or circumstance that might pose a risk to the subject or interfere with the ability to acquire satisfactory clinical data Pregnancy or breast-feeding History of proliferative diabetic retinopathy or macular edema Personal or family history of medullary thyroid carcinoma (MTC) or patients with multiple endocrine neoplasia syndrome type 2 (MEN 2)

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **38**

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

Ethics committee of Tehran University of Medical Sciences

Street address

Central Building, Tehran University of Medical Sciences, Keshavarz Boulevard, at the intersection of Qods Street, Tehran, Iran

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Approval date

2026-09-08, 1405/06/17

Ethics committee reference number

IR.TUMS.EMRI.REC.1405.070

Health conditions studied

1

Description of health condition studied

Diabetes type 1 and obesity

ICD-10 code

E10, E66.9

ICD-10 code description

Type 1 diabetes mellitus, Obesity

Primary outcomes

1

Description

Change in body weight from baseline after 12 weeks

Timepoint

Day 0, Week 12

Method of measurement

Weighting with scale

Secondary outcomes

1

Description

Proportion of patients with equal to or more than 5% weight loss at week 12

Timepoint

Day 0, Week 12

Method of measurement

Weighting with scale

2

Description

Percent change in body weight from baseline till week 12

Timepoint

Day 0, Week 12

Method of measurement

Weighting with scale

3

Description
Change from baseline in waist circumference (WC) at week 12
Timepoint
Day 0, Week 12
Method of measurement
Measurement by tape

4

Description
Change from baseline in fasting blood sugar (FBS) at week 12
Timepoint
Day 0, Week 12
Method of measurement
Laboratory test

5

Description
Change from baseline in HbA1C at week 12
Timepoint
Day 0, Week 12
Method of measurement
Laboratory test

6

Description
Change from baseline in total daily Insulin dose at week 12
Timepoint
Day 0, Week 12
Method of measurement
Insulin dose

7

Description
Change from baseline in total basal and bolus insulin dose (including rapid acting insulin types) at week 12
Timepoint
Day 0, Week 12
Method of measurement
Insulin dose

8

Description
Percent change from baseline in total daily Insulin dose at week 12
Timepoint
Day 0, Week 12
Method of measurement
Insulin dose

9

Description
Change from baseline to week 12 in glycemic variability assessed by continuous glucose monitoring (CGM)
Timepoint
Day 0, Week 12
Method of measurement
CGM

10

Description
Change from baseline to week 12 in percentage of time of blood glucose assessed by CGM in range (70-180 mg/dL)
Timepoint
Day 0, Week 12
Method of measurement
CGM

11

Description
Change from baseline to week 12 in percentage of time of blood glucose assessed by CGM >180 mg/dL
Timepoint
Day 0, Week 12
Method of measurement
CGM

12

Description
Change from baseline to week 12 in percentage of time of blood glucose assessed by CGM <70 mg/dL
Timepoint
Day 0, Week 12
Method of measurement
CGM

Intervention groups

1

Description
Following the completion of the one-month run-in period, the patient's eligibility for study participation will be reassessed, including a review of continuous blood glucose monitoring results. Treatment with Spartina® (Tirzepatide manufactured by CinnaGen Co.) will then be initiated at a dose of 2.5 mg using an autoinjector or pen injector. The medication will be administered subcutaneously once weekly in the periumbilical area, upper arm, or thigh. If the medication is well tolerated, the dose will be increased to 5 mg once weekly in the second month, at the discretion of the treating physician and in accordance with routine clinical practice. If clinically indicated based on the patient's condition, the dose may also be increased to 7.5 mg once weekly in the third month. The total treatment duration will be three months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
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Full name of responsible person
Dr. Alireza Esteghamati

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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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

Name of organization / entity
Zist Orchid Pharmed Co

Full name of responsible person
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Medical Department Manager

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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
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