Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study to evaluate the effectiveness and safety of Spartina® (Tirzepatide manufactured by CinnaGen Co.) in adolescents with obesity and weight-related comorbidities

Protocol summary

Study aim

The objectives of this study are to assess the effectiveness and safety of Spartina® in adolescents with obesity.

Design

Prospective, Interventional

Settings and conduct

This study will be conducted on 65 adolescents with obesity and at least one weight-related comorbidity who are candidates for treatment with Spartina® over 24 weeks. During this period, patients will have 8 visits. At each visit, the effectiveness of Spartina® will be evaluated with the changes in BMI, weight, and waist circumference. Furthermore, the effectiveness of Spartina® will be assessed by the percentage of patients achieving ≥ 5%, ≥10%, and ≥15% reduction of BMI. Also, at each visit, participants will be evaluated and asked about the occurrence of adverse events after starting Spartina® by their physicians.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1.Age between 12 and <18 years 2. Have obesity, with at least one weight-related comorbidity 3.Capable of giving informed consent by a legal representative and assent by a study participant Exclusion criteria: 1.Prior use of any GLP-1 agonist in the last 6 months 2.Any condition or circumstance that, according to the investigator, might pose a risk to the subject if they are enrolled or interfere with the ability to acquire satisfactory clinical data 3.Having undergone or planning to undergo a weight reduction procedure 4.Pregnancy or breastfeeding 5.Prepubertal stage 6.Personal or family history MTC or patients with MEN 2 7.Have T1DM

Intervention groups

Tirzepatide (2.5–15 mg once weekly); the weekly dose should be increased to 5 mg after the first month, if the dose escalation is tolerable for the participant. Any further increase in the weekly dose for each individual is based on the investigator’s opinion.

Main outcome variables

Weight BMI WC Dose of Spartina® Adverse events Hip circumference Neck circumference

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150303021315N45**
Registration date: **2026-10-08, 1405/07/16**
Registration timing: **prospective**

Last update: **2026-10-08, 1405/07/16**
Update count: **0**

Registration date

2026-10-08, 1405/07/16

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

recruiting

Funding source

Expected recruitment start date

2026-10-22, 1405/07/30

Expected recruitment end date

2027-01-20, 1405/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study to evaluate the effectiveness and safety of Spartina® (Tirzepatide manufactured by CinnaGen Co.) in adolescents with obesity and weight-related comorbidities

Public title
Study to evaluate Spartina® (Tirzepatide manufactured by CinnaGen Co.) in adolescents with obesity and weight-related comorbidities

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Male or female between 12 and <18 years of age Obesity, defined as BMI ≥ 95th percentile for age and sex (on age- and gender-specific growth chart for diagnosis of obesity) ORHave overweight, as defined by BMI ≥ 85th percentile but < 95th percentile for age and sex, on age- and sex-specific growth chart, with at least one weight-related comorbidity, including but not limited to: 1.Dyslipidemia 2.Prehypertension/Hypertension 3.Metabolic dysfunction-associated steatotic liver disease 4.Obstructive sleep apnea 5.Prediabetes 6.Type 2 Diabetes Mellitus (T2DM) with an HbA1C < 9% 7.Polyendocrine metabolic ovarian syndrome Capable of giving informed consent by a legal representative and assent by a study participant (when applicable)

Exclusion criteria:
Prior use of any GLP-1 agonist in the last 6 months Having undergone or planning to undergo a weight reduction procedure, such as, but not limited to: a.Gastric bypass b.Sleeve gastrectomy c.Restrictive bariatric surgeries d.Any other procedure intended to result in weight reduction Pregnancy or breastfeeding Prepubertal stage (Tanner stage 1) Personal or family history of medullary thyroid carcinoma (MTC) or patients with multiple endocrine neoplasia syndrome type 2 (MEN 2) Have type 1 diabetes mellitus Any condition or circumstance that, according to the investigator, might pose a risk to the subject if they are enrolled or interfere with the ability to acquire satisfactory clinical data

Age
From **12 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **65**

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
Iran University of Medical Sciences Ethics Committee

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2026-10-03, 1405/07/11

Ethics committee reference number
IR.IUMS.REC.1405.394

Health conditions studied

1

Description of health condition studied
Overweight and obesity

ICD-10 code
E66

ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Change in body mass index (BMI) standard deviation score (Z-score) from baseline until week 24

Timepoint
BMI: Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24

Method of measurement
Measuring height with a stadiometer, rounded to the nearest centimeterMeasuring weight with a scaleBMI = weight (Kg)/ Height (m2)Z-score will be calculated based on the LMS tables provided by WHO.

Secondary outcomes

1

Description

•Percentage of participants who achieve BMI reduction of ≥ 5% from baseline until week 12

Timepoint

BMI:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24

Method of measurement

Measuring height with a stadiometer and weight with a scaleBMI = weight (Kg)/ Height (m2)

2

Description

Percentage of participants who achieve BMI reduction of ≥ 5% from baseline until week 24

Timepoint

BMI:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24

Method of measurement

Measuring height with a stadiometer and weight with a scaleBMI = weight (Kg)/ Height (m2)

3

Description

Percentage of participants who achieve BMI reduction of ≥ 10% from baseline until week 12

Timepoint

BMI:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24

Method of measurement

Measuring height with a stadiometer and weight with a scaleBMI = weight (Kg)/ Height (m2)

4

Description

Percentage of participants who achieve BMI reduction of ≥ 10% from baseline until week 24

Timepoint

BMI:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24

Method of measurement

Measuring height with a stadiometer and weight with a scaleBMI = weight (Kg)/ Height (m2)

5

Description

Percentage of participants who achieve BMI reduction of ≥ 15% from baseline until week 12

Timepoint

BMI:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24

Method of measurement

Measuring height with a stadiometer and weight with a scaleBMI = weight (Kg)/ Height (m2)

6

Description

Percentage of participants who achieve BMI reduction of ≥ 15% from baseline until week 24

Timepoint

BMI:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24

Method of measurement

Measuring height with a stadiometer and weight with a scaleBMI = weight (Kg)/ Height (m2)

7

Description

Percent change in BMI from baseline until week 24

Timepoint

BMI:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24

Method of measurement

Measuring height with a stadiometer and weight with a scaleBMI = weight (Kg)/ Height (m2)

8

Description

Absolute change in BMI from baseline until week 24

Timepoint

BMI:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24

Method of measurement

Measuring height with a stadiometer and weight with a scaleBMI = weight (Kg)/ Height (m2)

9

Description

Percent change in body weight from baseline until week 12

Timepoint

Body weight:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24

Method of measurement

Measuring weight with a scale

10

Description

Absolute change in body weight from baseline until week 12

Timepoint

Body weight:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24

Method of measurement

Measuring weight with a scale

11

Description

Percent change in body weight from baseline until week 24

Timepoint

Body weight:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24

Method of measurement
Measuring weight with a scale

12

Description
Absolute change in body weight from baseline until week 24
Timepoint
Body weight:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24
Method of measurement
Measuring weight with a scale

13

Description
Percent change in waist circumference (WC) from baseline until week 24
Timepoint
WC:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24
Method of measurement
Measuring WC with a tape meter

14

Description
Absolute change in WC from baseline until week 24
Timepoint
WC:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24
Method of measurement
Measuring WC with a tape meter

15

Description
Percent change in WC from baseline until week 12
Timepoint
WC:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24
Method of measurement
Measuring WC with a tape meter

16

Description
Absolute change in WC from baseline until week 12
Timepoint
WC:Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24
Method of measurement
Measuring WC with a tape meter

17

Description
Assessment of the adverse events (including treatment-emergent adverse events) based on the investigator's opinion during the study period
Timepoint
Screening, Week 4, Week 8, Week 12, Week 16, Week 20 & Week 24
Method of measurement
Adverse events occurred during the study based on physician assessment

Intervention groups

1

Description
Intervention group: Pre-filled syringes of Spartina® (Tirzepatide manufactured by CinnaGen Co.) will be prescribed and injected subcutaneously once a week with a dose starting from 2.5 mg/weekly and titrated up based on the physician's opinion
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Asghar Children's Hospital
Full name of responsible person
Dr. Fahimeh Soheilipour
Street address
Tehran, Modares Highway (North), Shahid Vahid Dastgerdi Street (formerly Zafer), No. 193.
City
Tehran
Province
Tehran
Postal code
۱۹۱۹۸۱۶۷۶۳
Phone
+98 912 945 2311
Email
fsoheilipour@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
CinnaGen Company
Full name of responsible person
Mehran Montajabi Niyat
Street address
Alborz Province, Fardis County, Simin Dasht Industrial Town, 9th Western Street, No. 72, Ground Floor.
City
Tehran
Province
Tehran
Postal code
3165933155
Phone
+98 21 4291 5000

Email
info@cinnagen.com
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
Full name of responsible person
Dr. Hamidreza Kafi
Position
Medical Manager
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Postal code
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Fahimeh Soheilipour
Position
Professor of Pediatric Endocrinology & Metabolism
Latest degree
Medical doctor
Other areas of specialty/work
Professor of Pediatric Endocrinology & Metabolism
Street address
Tehran, Modares Highway (North), Shahid Vahid Dastgerdi Street (formerly Zafer), No. 193.
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Person responsible for updating data

Contact
Name of organization / entity
Orchid Pharmed Company
Full name of responsible person
Dr. Hamidreza Kafi
Position
Pharmacist (PharmD), Medical Manager
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, Tehran, Iran
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1994766411
Phone
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Fax
Email
Kafi.H@orchidpharmed.com
Web page address

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