

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

A randomized, two-armed, parallel, active-controlled clinical trial to compare equivalent efficacy along with safety, and immunogenicity of CinnaTropin® (CinnaGen, Iran) to Norditropin® NordiLet® (Novo Nordisk, Denmark) in pre-pubertal children with growth hormone deficiency (GHD)

Protocol summary

Study aim

This study aims to compare equivalent efficacy along with safety, and immunogenicity of CinnaTropin® to Norditropin® NordiLet® in children with growth hormone deficiency.

Design

This phase III study is a randomized, two-armed, parallel, and active-controlled clinical trial to compare equivalent efficacy along with safety, and immunogenicity of CinnaTropin® to Norditropin® NordiLet® in pre-pubertal children with growth hormone deficiency.

Settings and conduct

This study will be conducted in 17 cities and 33 centers in Iran. In this phase 3 study, after providing informed consent, 102 pre-pubertal patients with growth hormone deficiency will be evaluated regarding inclusion and exclusion criteria. After fulfilling the criteria patients will receive a randomization code, and be randomly assigned to one of the arms of CinnaTropin or Norditropin NordiLet. Patients will receive the treatments for 12 months.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: GH-naïve; Prepubertal; male children aged 3-10 and female children 3-8 years; Isolated idiopathic growth hormone (GH) deficiency diagnosed; Peak GH < 10.0 µg/l following two recommended GH stimulation tests; Height Standard Deviation Score (HSDS) ≤ -2.0 and Height Velocity SDS ≤ -1.0; or HSDS ≤ -3.0; bone age to chronological age ratio < 0.9; Full-term birth weight > 2500g; Euthyroid. Exclusion Criteria: Chronic systemic disease; Evidence of active tumor; Chromosomal or skeletal abnormalities; Signs of idiopathic intracranial hypertension; Closed epiphyses; Chronic use of oral or parenteral glucocorticoid in the last three years; Using methylphenidate in the last 14 days

Intervention groups

Daily injection of 0.03 mg/kg of CinnaTropin Daily injection of 0.03 mg/kg of Norditropin NordiLet

Main outcome variables

Change in height velocity (cm/year)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150303021315N12**

Registration date: **2019-04-07, 1398/01/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-07, 1398/01/18**

Update count: **0**

Registration date

2019-04-07, 1398/01/18

Registrant information

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Name of organization / entity

Orchid Pharmed

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-14, 1397/09/23

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized, two-armed, parallel, active-controlled clinical trial to compare equivalent efficacy along with safety, and immunogenicity of CinnaTropin® (CinnaGen, Iran) to Norditropin® NordiLet® (Novo Nordisk, Denmark) in pre-pubertal children with growth hormone deficiency (GHD)

Public title

Comparing CinnaTropin® with Norditropin® NordiLet® in pre-pubertal children with growth hormone deficiency

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

GH-naïve Prepubertal (Tanner stage I) 3 to 10 years of age for male children and 3 to 8 years of age for female children Isolated idiopathic growth hormone deficiency diagnosed Peak growth hormone value of <10.0 µg/l following two recommended growth hormone stimulation tests Height Standard Deviation Score (HSDS) ≤ -2.0 and Height Velocity Standard Deviation Score (HVSDS) ≤ -1.0; or HSDS ≤ -3.0 The ratio of bone age to chronological age < 0.9 Full-term birth weight above 2500 g Euthyroid state

Exclusion criteria:

Chronic systemic disease, such as diabetes mellitus or renal disease Evidence of active tumor Chromosomal or skeletal abnormalities Signs of idiopathic intracranial hypertension Closed epiphyses Chronic use of oral or parenteral glucocorticoid in the past three months Using methylphenidate in the last 14 days

AgeFrom **3 years** old to **10 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **102****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 102 patients (1:1 allocation ratio). After the randomization procedure, a code will be allocated to each patient that will be used as a patient-identifier throughout the study. The assigned code will be denoted by 4 initials (corresponding to the first two

letters of the first name, first two letters of surname) and 3 numbers (center code). Moreover, the code described is followed by the study unique identification code consisting of first three letters of the name of the investigational product (which is CIN-) and three numbers (corresponding to the randomization number), e.g. ABCD001CIN-001. The randomization number will be assigned in a consecutive way.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Tehran University of Medical Sciences

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Sixth floor, Research Deputy of Tehran University of Medical Sciences, Ghods Street, Keshavarz Boulevard

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Approval date

2018-08-25, 1397/06/03

Ethics committee reference number

IR.TUMS.VCR.REC.1397.363

Health conditions studied**1****Description of health condition studied**

Isolated idiopathic growth hormone deficiency

ICD-10 code

E23.0

ICD-10 code description

Hypopituitarism

Primary outcomes**1****Description**

Change in height velocity

Timepoint

Prior to intervention and 12 months after the first

intervention

Method of measurement

wall-mounted stadiometer

Secondary outcomes

1

Description

Change in height

Timepoint

Prior to intervention and 12 months after the first intervention

Method of measurement

wall-mounted stadiometer

2

Description

Change in weight

Timepoint

Prior to intervention and 12 months after the first intervention

Method of measurement

Weight measuring device

3

Description

Change in Height Standard Deviation Score (HSDS)

Timepoint

Prior to intervention and 12 months after the first intervention

Method of measurement

Centers for Disease Control and Prevention clinical growth data

4

Description

Safety

Timepoint

At screening visit, first intervention, and 3, 6, 9, and 12 months after the first intervention

Method of measurement

Patient's history, physical examination, and laboratory data

5

Description

Immunogenicity

Timepoint

Prior to first intervention and at 3, 6, 9, and 12 months after the first intervention

Method of measurement

Evaluation of the presence and titre of anti-drug antibody in the blood sample

Intervention groups

1

Description

Control group: CinnaTropin® pen-injector (5 mg/1.5 mL, CinnaGen, Iran), SC injection of 0.03 mg/kg for one year

Category

Treatment - Drugs

2

Description

Control group: Norditropin® NordiLet® pen (5 mg/1.5 mL, Novo Nordisk, Denmark), SC injection of 0.03 mg/kg for one year

Category

Treatment - Drugs

Recruitment centers

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Recruitment center

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Sponsors / Funding sources

1

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Name of organization / entity

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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

Orchid Pharmed Company

Full name of responsible person

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Position

Pharmacist, Clinical Trial Manager

Latest degree

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Other areas of specialty/work

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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