Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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<10.0µg/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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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
Age
From **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 Boulvard
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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

1

Recruitment center

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Sponsors / Funding sources

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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

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Dr. Nasim Anjidani
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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