

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Safety and Efficacy of CinnaGen Human Recombinant Growth Hormone in Comparison with Novo Nordisk Growth Hormone in Children with Idiopathic Growth Hormone Deficiency: A Randomized Clinical Trial

Protocol summary

Summary

The main objective is the comparison of safety and efficacy of Iranian recombinant growth hormone (CinnaGen) with Novo Nordisk brand. This unblinded study will be conducted in Ali Asghar Children Hospital, Tehran. A total of 30 children with growth hormone deficiency (before puberty) will take part in this clinical trial. Inclusion criteria: age between 4 and 16 years, pre-pubertal or early puberty stage; height standard deviation score < -2 in diagnosis time; growth hormone level post stimulating test by clonidine < 10 ng/ml; rule out of the other causes of growth hormone deficiency; Documented Pituitary or hypothalamic hormone deficiency or low normal serum IGF-1 at the time of diagnosis; In case of the deficiency in other pituitary hormones, the patient can only be included, if the replacement of other pituitary hormones was done. Exclusion criteria: acute or systemic disorders such as seizure, infectious diseases, chronic pulmonary infection, AIDS, chronic liver disease; Turner syndrome, chronic kidney disease; Any active malignancy; Contraindications of the administration of growth hormone (sleep apnea syndrome); Short stature due other causes of GHD; History of diabetes in patient or his/her first-degree relatives; prednisolone usage except for replacement therapy. Children will be allocated in two groups by simple randomisation method and will receive growth hormone of CinnaGen or Novo Nordisk in a cross-over design with a starting dose of subcutaneous injection every night 0.03 mg/kg/day. On each monthly visit, complete physical examination will be done and the maturity of the child will be assessed by the classification of Tanner. Children will receive a total of 6 months of drug intervention, three months in the intervention group with CinnaGen growth hormone and three months in the comparison group with Novo Nordisk growth hormone and vice versa in the next three months. Growth velocity

(GV) will be the primary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409064920N5**

Registration date: **2015-07-10, 1394/04/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-07-10, 1394/04/19

Registrant information

Name

Ramin Heshmat

Name of organization / entity

Chronic Diseases Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 0086

Email address

rheshmat@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

CinnaGen Pharmaceutical Company (Sponsor)

Expected recruitment start date

2016-03-01, 1394/12/11

Expected recruitment end date

2016-12-30, 1395/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Safety and Efficacy of CinnaGen Human Recombinant Growth Hormone in Comparison with Novo Nordisk Growth Hormone in Children with Idiopathic Growth Hormone Deficiency: A Randomized Clinical Trial

Public title
Comparison of the effects and adverse events of CinnaGen recombinant human growth hormone & Novo Nordisk growth hormone in children with growth hormone deficiency

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: age between 4 and 16 years, pre-pubertal or early puberty stage; height standard deviation score < -2 in diagnosis time; growth hormone level post stimulating test by clonidine < 10 ng/ml; rule out of the other causes of growth hormone deficiency; Documented Pituitary or hypothalamic hormone deficiency or low normal serum IGF-1 at the time of diagnosis; In case of the deficiency in other pituitary hormones, the patient can only be included, if the replacement of other pituitary hormones was done
Exclusion criteria: acute or systemic disorders such as seizure, infectious diseases, chronic pulmonary infection, AIDS, chronic liver disease; Turner syndrome, chronic kidney disease; Any active malignancy; Contraindications of the administration of growth hormone (sleep apnea syndrome); Short stature due other causes of GHD; History of diabetes in patient or his/her first-degree relatives; prednisolone usage except for replacement therapy.

Age
From **4 years** old to **16 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Research Deputy Building, Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Postal code

14144

Approval date

2016-04-16, 1395/01/28

Ethics committee reference number

IR.IUMS.REC.1395.27183

Health conditions studied

1

Description of health condition studied

Idiopathic Growth Hormone Deficiency

ICD-10 code

E23.0

ICD-10 code description

Hypopituitarism

Primary outcomes

1

Description

Growth velocity

Timepoint

before intervention and at 3rd and 6th months of intervention

Method of measurement

assessment of height changes in time unit

Secondary outcomes

1

Description

Height Standard Deviation Score (HSDS)

Timepoint

before intervention and in 3rd and 6th month of intervention

Method of measurement

Growth Calculator 2.01

2

Description

Height Velocity Standard Deviation Score (HVSDS)

Timepoint

At the end of 3rd and 6th month of intervention

Method of measurement

Growth Calculator 2.01

3**Description**

The incidence of Adverse Events

Timepoint

befor intevention and in 3rd and 6th month of intervention

Method of measurement

Case report forms

4**Description**

Weight

Timepoint

befor intevention and in 3rd and 6th month of intervention

Method of measurement

Scale

5**Description**

Stutre status

Timepoint

befor intevention and in 3rd and 6th month of intervention

Method of measurement

Studiometer

Intervention groups**1****Description**

Intervention group: administration of 0.03 mg/kg/day of CinnaGen recombinant growth hormone, by subcutaneous injection for 3 months

Category

Treatment - Drugs

2**Description**

Control group: administration of 0.03 mg/kg/day of Novo Nordisk recombinant growth hormone, by subcutaneous injection for 3 months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ali Asghar Peditaterics Hospital

Full name of responsible person

Dr Maryam Razaghi Azar

Street address

Dasgerdi Ave, Modarres Highway

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

CinnaGen Pharmaceutical Company

Full name of responsible person

Dr Hale Hamedifar

Street address

2 No,7 th allay, Simaye Iran St, Shahrak Gharb(Ghods)

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

CinnaGen Pharmaceutical Company

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Chronic Diseases Research Center

Full name of responsible person

Dr Ramin Heshmat

Position

Epidemiologist/ Head of research center

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Inborn Metabolic Disorders Research Center

Full name of responsible person

Dr Maryam Razaghi Azar

Position

Prof. of Pediatrics Endocrinology

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Contact

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Chronic Diseases Research Center

Full name of responsible person

Maryam Sanaei

Position

MSc. Cilinical Research Manager

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty