Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 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

Idiopatic Growth Hormone Dificiency

ICD-10 code

E23.0

ICD-10 code description

Hypopituitarism

Primary outcomes

1

Description

Growth velocity

Timepoint

befor 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

befor intevention 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 Pediaterics 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
4th Floor, no. 111, 19th St, North Kargar Ave.
City
Tehran
Postal code
Phone
+98 21 8835 4327
Fax
Email
rheshmat@tums.ac.ir
Web page address

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

Other areas of specialty/work

Street address
Ali Asghar Hospital, Dastgerdi Ave, Modarres Highway

City
Tehran

Postal code

Phone
+98 21 2222 2041

Fax

Email
mazar_md@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Chronic Diseases Research Center

Full name of responsible person
Maryam Sanaei

Position
MSc. Cilinical Research Manager

Other areas of specialty/work

Street address
2nd fl, No 111, 19th St, North Kargar Ave.

City
Tehran

Postal code

Phone
+98 21 8835 4327

Fax

Email

Web page address

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