Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the short & long term effects and side effects of Samen recombinant human growth hormone & NOVO growth hormone in children with growth hormone deficiency: double-blind randomized clinical trial study

Protocol summary

Summary

In this Randomized Clinical Trial, after randomization children to two groups for giving NOVO recombinant growth hormone or Samen recombinant growth hormone, we will evaluate children for 2 years. Our lababoratory tests include complete blood cell, blood urea nitrogen, creatinine,Na,potassium, insulin growth factor-1,Serum glutamic oxaloacetic transaminase,Serum glutamic pyruvic transaminase,alkaline phosphatase, phosphor,25-hydroxy vitamin D,bone age,height, weight, height standard deviation score, weight standard deviation score ,pubertal stage before starting study. We will repeat most of above exams in 1 month, 2 month, 3 month, 4month, 5 month, 6 month,12 month, 18 month, and finally in 24 month. We will record growth velocity in these times. Finally compare the results of these two groups and report them.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT1138901181414N11**
Registration date: **2010-09-14, 1389/06/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-09-14, 1389/06/23

Registrant information

Name

Bagher Larijani

Name of organization / entity

Endocrinology & Metabolism Research Center, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 0037

Email address

emrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Samen Pharmaceutical Co. /Mashhad-Iran

Expected recruitment start date

2006-08-01, 1385/05/10

Expected recruitment end date

2011-08-01, 1390/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the short & long term effects and side effects of Samen recombinant human growth hormone & NOVO growth hormone in children with growth hormone deficiency: double-blind randomized clinical trial study

Public title

Comparison of the clinical & treatment effects of Samen recombinant human growth hormone & NOVO growth hormone in children with growth hormone deficiency

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: 1-Pre-pubertal stage 2-Height standard

deviation score<-3 3-Insulin growth factor-1 inappropriate for age & sex (low) 4-Growth hormone level post stimulating test by clonidine <10 ng/ml 5-Rule out of the other causes of growth hormone deficiency exclusion criteria: 1-Acute disorders such as seizure, infection diseases 2-Turner syndrome 3-Chronic kidney disease 4-Usage prednisolone

Age
From **7 years** old to **13 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Endocrinology & Metabolism Research Center(EMRC) of TUMS

Street address
5th filoor,Dr.Sharati Hospital, North Karegar St.

City
tehran

Postal code
14114

Approval date
empty

Ethics committee reference number
E-0096

Health conditions studied

1

Description of health condition studied
Growth hormone deficiency in children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Growth velocity

Timepoint
1 year

Method of measurement
assessment height, puberty status

Secondary outcomes

1

Description
Insulin growth factor-1,bone age

Timepoint
6 month

Method of measurement
blood sample, radiology

Intervention groups

1

Description
treatment intervention by 0.04 mg/kg/day Samen recombinant growth hormone in subcutaneous way for one year in intervention group

Category
Treatment - Drugs

2

Description
treatment intervention by daily subcutaneous injection 30 microgram/kilogram weight of NOVO recombinant growth hormone for one year in control group

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrinology & Metabolism Research Center (EMRC) of TUMS

Full name of responsible person
Dr. Ozra Tabatabaei Malazy

Street address
5th floor, Dr. Sharati Hospital, North Karegar St.

City
tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pharmacy CO. Samen

Full name of responsible person

Dr. Mohamad Ramezani

Street address

Mashhad

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Pharmacy CO. Samen

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Endocrinology & Metabolism Research Center of Tehran University of Medical Sciences

Full name of responsible person

Dr.Bagher Larijani

Position

Prof. Endocrinology

Other areas of specialty/work

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5th floor, dr. Shariati Hospital, North Karegar st.

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Endocrinology & Metabolism Research Center of Tehran University of Medical Sciences

Full name of responsible person

Dr. Ozra Tabatabaei Malazy

Position

Medical Doctor, Master of Public Health

Other areas of specialty/work

Street address

City

Postal code

Phone

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