

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Determining efficacy and safety of recombinant growth hormone Somatin® (AryaTinaGene) compared to Norditropin® (Novonordisk) in children with growth hormone deficiency: A non-inferiority phase III randomized parallel clinical trial

Protocol summary

Study aim

Efficacy and safety assessment of AryaTinaGen recombinant Growth Hormone, in comparison with Norditropin in growth hormone deficient children

Design

Parallel non-inferiority phase III, randomized clinical trial

Settings and conduct

This study will be performed on children with growth hormone deficiency in 10 centers located in 14 cities (Tehran, Gorgan, Mashhad, Tabriz, Isfahan, Rasht, Babol, Sari, Kerman, Ahvaz, Karaj, Shiraz, Qazvin and Kermanshah). the main recruitment center is Taleghani hospital in Gorgan. Patients will be recruited according to inclusion and exclusion and complete the informed consent form as well as initial examinations and lab tests (including, hematology and biochemistry tests and wrist x-ray). Then patients will fall into one of the two groups of intervention or control, based on the randomization list. After the first injection, the related measurements will be repeated. Possible adverse events will be also recorded. In both groups, patients undergo clinical examinations and laboratory tests every three months

Participants/Inclusion and exclusion criteria

Inclusion criteria of the study is short stature defined as children who have height standard deviation score (HSDS) < -3SD, Exclusion criteria are hypothyroidism, celiac, seizure, , any chronic systemic disorders such as diabetes mellitus , sleep apnea syndrome, pervious GH replacement therapy, and concomitant use of corticosteroid.

Intervention groups

Intervention group: Biosimilar recombinant growth hormone (Somatin) 35 µg/kg/d, subcutaneous injection.
Control group: Norditropin recombinant growth hormone 35 µg/kg/d, subcutaneous injection

Main outcome variables

Height velocity in the first year after treatment

General information

Reason for update

Changes because of the food and drug administration requirements, updating recruitment centers and actual recruitment dates

Acronym

IRCT registration information

IRCT registration number: **IRCT20171122037571N1**
Registration date: **2019-03-05, 1397/12/14**
Registration timing: **prospective**

Last update: **2022-09-13, 1401/06/22**

Update count: **2**

Registration date

2019-03-05, 1397/12/14

Registrant information

Name

Hamed Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 5503

Email address

hmdhosseini@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-05, 1398/02/15

Expected recruitment end date

2020-03-05, 1398/12/15
Actual recruitment start date
 2020-05-19, 1399/02/30
Actual recruitment end date
 2021-03-16, 1399/12/26
Trial completion date
 empty

Scientific title
 Determining efficacy and safety of recombinant growth hormone Somatin® (AryaTinaGene) compared to Norditropin® (Novonordisk) in children with growth hormone deficiency: A non-inferiority phase III randomized parallel clinical trial

Public title
 Determining efficacy and safety of recombinant growth hormone Somatin® (AryaTinaGene) compared to Norditropin® (Novonordisk) in children with growth hormone deficiency

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Children older than 2 and younger than 10 for girls and 11 for boys. Short stature with height standard deviation score (HSDS) < -3SD, No increase in growth hormone more than 10 or 20 mIU/L after fasting and clonidine stimulating test Signing the written informed consent by the gradians and assent by children older than 7
Exclusion criteria:
 Any history of using GH or history of using estrogen of adrenal androgens within last year. History of seizure, sleep apnea syndrome or other respiratory disorders. Concomitant use of corticosteroid Any chronic systemic disorders such as hypothyroidism, DM, rickets, skeletal dysplasia, pervious chromosomal abnormalities Sensitivity to GH History of chemotherapy of radiotherapy Children with psychosocial dwarfism or idiopathic or familial short stature Children with idiopathic or familial short stature Spinal disorders such as scoliosis, kyphosis, chiari malformation, spinabifida variations

Age
 From **2 years** old to **11 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
 Target sample size: **80**
 Actual sample size reached: **80**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Random Chain Generation performed using by (<https://www.sealedenvelope.com>) We used randomized permutations, blocks (the size of each block is 4) for a

total of 80 volunteers (1: 1 ratio). The codes will be labeled on the drugs. After ensuring the volunteer's eligibility and signing the informed consent form, a nurse will receive a code from the study site which will be used for random allocation of the drug to the candidate. The related drug will be used for the volunteer. In this way, the volunteers fall into one of the two intervention groups and the volunteers' group and the type of drug they receive will not be disclosed to researchers or the study team

Blinding (investigator's opinion)

Single blinded

Blinding description

In this clinical trial, blindness can not be fully accomplished (due to the brand's exclusive form of this drug, this is not possible for any study), but we try to minimize the information sources for different individuals in the study to prevent the Information bias. For this purpose, syringes containing both drugs are packaged with code only. Researchers who prescribe medication, those who provide the drug to patients, and those who are responsible for the examination and evaluation of patients, will be unaware of the nature of the syringes, and during this study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Room 105 , 5th floor, Central construction of Tehran University of Medical Sciences, Ghods intersection, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-01-30, 1397/11/10

Ethics committee reference number

IR.TUMS.VCR.REC.1397.854

2

Ethics committee

Name of ethics committee

Golestan University of Medical sciences

Street address

Hirkan Blvd, Gorgan

City
Gorgan
Province
Golestan
Postal code
4931171756
Approval date
2018-11-13, 1397/08/22
Ethics committee reference number
IR.GOUMS.REC.1397.173

Health conditions studied

1
Description of health condition studied
Short stature due to endocrine disorder
ICD-10 code
E34.3
ICD-10 code description
Short stature due to endocrine disorder

Primary outcomes

1
Description
Body height
Timepoint
Before treatment and 3, 6, 9 and 12 months later
Method of measurement
Using harpenden wall mounted stadiometer

Secondary outcomes

1
Description
Insulin-Like Growth Factor 1 serum level
Timepoint
Before treatment and 6 and 12 months later
Method of measurement
Hematology lab test

2
Description
Insulin-like growth factor-binding protein 3 serum level
Timepoint
Before treatment and 6 and 12 months later
Method of measurement
Hematology lab test

3
Description
bone age wrist
Timepoint
Before treatment and 12 months later
Method of measurement
Left wrist x-ray

4
Description
Weight
Timepoint
Before treatment and 3,6,9 and 12 months later
Method of measurement
Scale

Intervention groups

1
Description
Intervention group: AryaTinaGen recombinant Growth Hormone, 35µg/kg/d, subcutaneous injection
Category
Treatment - Drugs

2
Description
Control group: Norditropin recombinant Growth Hormone 35 µg/kg/d, subcutaneous injection
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
Taleghani children hospital in Gorgan
Full name of responsible person
Hossein Zaeri
Street address
Janbazan boulevard
City
Gorgan
Province
Golestan
Postal code
4979146595
Phone
+98 17 3222 7720
Email
dr.zaeri@yahoo.com

2
Recruitment center
Name of recruitment center
Imam Hossein children hospital
Full name of responsible person
Dr. Mahin Hashemipoor
Street address
Imam Khomeini street
City
Isfahan
Province
Isfahan
Postal code

1111111111

Phone

+98 31 3386 6266

Email

dr.zaeri@yahoo.com

3

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Dr. Peyman Eshraghi

Street address

Ibn Sina street

City

Mashhad

Province

Razavi Khorasan

Postal code

1111111111

Phone

+98 51 3854 3031

Email

dr.zaeri@yahoo.com

4

Recruitment center

Name of recruitment center

Iranian clinic

Full name of responsible person

Dr. Serajaddin Arefnia

Street address

15th Edalat street

City

Gorgan

Province

Golestan

Postal code

1111111111

Phone

+98 17 3233 8388

Email

dr.zaeri@yahoo.com

5

Recruitment center

Name of recruitment center

Children's hospital

Full name of responsible person

Dr. Robabeh Ghergherehchi

Street address

Sheshgelan street

City

Tabriz

Province

East Azarbaijan

Postal code

1111111111

Phone

+98 41 3526 2255

Email

dr.zaeri@yahoo.com

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Recruitment center

Name of recruitment center

Dr. Dalili's clinic

Full name of responsible person

Dr. Setila Dalili

Street address

No. 48, 161st street, Gilan boulevard

City

Rasht

Province

Guilan

Postal code

1111111111

Phone

+98 13 3312 9091

Email

dr.zaeri@yahoo.com

7

Recruitment center

Name of recruitment center

Baran Clinic

Full name of responsible person

Dr. Elham Maleki

Street address

Jahad boulevard

City

Kerman

Province

Kerman

Postal code

7619817189

Phone

+98 34 3223 5543

Email

dr.zaeri@yahoo.com

8

Recruitment center

Name of recruitment center

Mohamad Kermanshahi hospital

Full name of responsible person

Dr. Mahmoud Ghasemi

Street address

Hilal-Ahmar intersection

City

Kermanshah

Province

Kermanshah

Postal code

6713733135

Phone

+98 83 3721 8202

Fax

Email

dr.zaeri@yahoo.com

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Recruitment center

Name of recruitment center

Bahonar hospital

Full name of responsible person

Dr. Shahab Noorian

Street address

Azimieh three-way

City

Karaj

Province

Alborz

Postal code

1111111111

Phone

+98 26 3250 9256

Email

dr.zaeri@yahoo.com

10

Recruitment center

Name of recruitment center

Imam Reza clinic

Full name of responsible person

Dr. Hossein Moravej

Street address

Namazi square

City

Shiraz

Province

Fars

Postal code

۱۴۷۳۴۷۱۳۴۸

Phone

+98 71 3647 4673

Email

dr.zaeri@yahoo.com

11

Recruitment center

Name of recruitment center

Qods hospital

Full name of responsible person

Dr. Abdollah Didban

Street address

Qods square

City

Qazvin

Province

Qazvin

Postal code

1111111111

Phone

+98 28 3333 4807

Email

dr.zaeri@yahoo.com

12

Recruitment center

Name of recruitment center

Eram Clinic

Full name of responsible person

Dr. Hoseinali Kharazmi

Street address

North Golshahr street

City

Bandarabas

Province

Hormozgan

Postal code

1111111111

Phone

+98 76 3363 4345

Email

dr.zaeri@yahoo.com

13

Recruitment center

Name of recruitment center

Rasool Akram hospital

Full name of responsible person

Dr. Fahimeh Soheilipoor

Street address

Niayesh Street

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 8888 6350

Email

dr.zaeri@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arya Tina Gene company

Full name of responsible person

Mohammad Ali Afshari

Street address

1st floor, No. 3, 2nd dead end, Hamsian street, West

Keshavarz boulevard

City

Tehran

Province

Tehran

Postal code

1418753471

Phone

+98 21 6642 5137

Email

info@atgbio.com

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

organization/entity?

Yes

Title of funding source

Arya Tina Gene 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**

Tehran University of Medical Sciences

Full name of responsible person

Ayat Ahmadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

23rd unit, 4th floor, No 1547, North Kargar Street,

City

Tehran

Province

Tehran

Postal code

1417993337

Phone

+98 21 8896 3546

Email

ayat1049@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Hossein Zarei

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinologist

Street address

Taleghani children hospital, Janbazan Blvd, Gorgan

City

Tehran

Province

Tehran

Postal code

4979146595

Phone

+98 17 3222 7720

Email

dr.zaeri@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

23rd unit, 4th floor, No 1547, North Kargar Street

City

Tehran

Province

Tehran

Postal code

1417993337

Phone

+98 21 8896 3546

Email

aniseh_samadi@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available