

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation of estrogen therapy on final height of short girls with chronic kidney disease (CKD) and delayed puberty

Protocol summary

Study aim

Determining the effect of estrogen therapy on the final height of short girls with chronic kidney disease (CKD) and delayed puberty

Design

A clinical trial with control group, with parallel groups, without blinding, without randomization, phase 3 on 75 patients.

Settings and conduct

This study is conducted on 75 children with CKD referred to Aliasghar children's Hospital. Children are divided into 3 groups. In the first intervention group, growth hormone and estrogen are prescribed from the age of 11 years. In the second intervention group, hormones and estrogen are prescribed from the age of 13 years. In the control group, patients do not receive growth hormone and estrogen until the age of 15, blinding is not performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: consent to participate in the study, patients with chronic kidney disease (CKD), girls with short stature, beginning of dialysis around 3.5 to 5 years. Exclusion criteria: Incidence of puberty before the estrogen therapy, kidney transplantation before the study.

Intervention groups

In the first intervention group, patients receive injection of growth hormone (Genotropin manufactured by Pfizer, US), at the rate of 0.05 mg/kg, once a day for 4-6 years and oral Estrogen (Ethinyl Estradiol, manufactured by Aburaihan, Iran) from the age of 11 at the rate of 5 µg once a day until the age of 16. In the second intervention group, patients receive injection of growth hormone (Genotropin manufactured by Pfizer, US), at the rate of 0.05 mg/kg, once a day for 4-6 years and oral Estrogen (Ethinyl Estradiol, manufactured by Aburaihan, Iran) from the age of 13 at the rate of 5 µg once a day until the age of 16. In the control group, patients do not receive growth hormone and estrogen until the age of 15

Main outcome variables

Final height after 15 years old

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201110049334N1**

Registration date: **2021-01-30, 1399/11/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-30, 1399/11/11**

Update count: **0**

Registration date

2021-01-30, 1399/11/11

Registrant information

Name

Davood Amirkashani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2304 6253

Email address

amirkashani.d@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of estrogen therapy on final height of short girls with chronic kidney disease (CKD) and delayed puberty

Public title

Evaluation of estrogen therapy on the height of children with chronic kidney disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient and parent consent to participate in the study. Patients with chronic kidney disease (CKD). Patients must be girls. With short stature (height and growth velocity respectively below 3th and 25th percentile for more than 1 year). In all patients, beginning of dialysis around 3.5 to 5 years. Growth hormone has been started in all patients from the age of 5.5 to 8 years, despite therapeutic indications.

Exclusion criteria:

Incidence puberty before the estrogen therapy Kidney transplantation before the study

Age

From **3 years** old to **7 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Ethics committee of Iran University of Medical Sciences

Street address

Next to the Milad Tower, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1453514496

Approval date

2020-10-26, 1399/08/05

Ethics committee reference number

IR.IUMS.REC.1399.708

Health conditions studied

1

Description of health condition studied

Short stature

ICD-10 code

N25

ICD-10 code description

Disorders resulting from impaired renal tubular function

Primary outcomes

1

Description

Final height after 15 years old

Timepoint

Before the intervention and after the age of 15

Method of measurement

Height gauge

Secondary outcomes

1

Description

Bone density

Timepoint

Before the intervention and after the age of 15

Method of measurement

Dexa bone densitometry

Intervention groups

1

Description

First intervention group: In this group, patients (N = 25) receive injection of growth hormone (Genotropin manufactured by Pfizer, US) from the beginning of short stature, at the rate of 0.05 mg/kg, once a day for 4-6 years and oral Estrogen (Ethinyl Estradiol, manufactured by Aburaihan, Iran) from the age of 11 at the rate of 5 µg (it will double every 3 to 6 months until to reach a dose of 30 µg) once a day and continues until the age of 16.

Category

Treatment - Drugs

2

Description

Second intervention group: In this group, patients (N = 25) receive injection of growth hormone (Genotropin manufactured by Pfizer, US) from the beginning of short stature, at the rate of 0.05 mg/kg, once a day for 4-6 years and oral Estrogen (Ethinyl Estradiol, manufactured by Aburaihan, Iran) from the age of 13 at the rate of 5 µg (it will double every 3 to 6 months until to reach a dose of 30 µg) once a day and continues until the age of 16.

Category

Treatment - Drugs

3

Description

Control group: in this group patients (N = 25) do not receive growth hormone and estrogen until the age of 15 and are the same with both intervention groups in terms of age, sex, average parental height and stage of chronic kidney disease (There is no intervention in this group).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Aliasghar Children's Hospital

Full name of responsible person

Davod Amirkashani

Street address

No193, zafar St, Modares Highway

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6253

Email

amirkashani.d@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abbas Motevalian

Street address

Next to the Milad Tower, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1453514496

Phone

+98 21 8670 2503

Email

motevalian.a@iums.ac.ir

Grant name

Aliasghar Clinical Research Development Center

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

No

Title of funding source

Iran University of Medical sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Davod Amirkashani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

No193, zafar St, Modares Highway

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6253

Email

amirkashani.d@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Davod Amirkashani

Position

Assistant professor

Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
No193, zafar St, Modares Highway.
City
Tehran
Province
Tehran
Postal code
1919816766
Phone
+98 21 2304 6253
Email
amirkashani.m@iums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Davod Amirkashani
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
No193, zafar St, Modares Highway.
City

Tehran
Province
Tehran
Postal code
1919816766
Phone
+98 21 2304 6253
Email
amirkashani.d@iums.ac.ir

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