

# 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  
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## 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