

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The therapeutic effect of testosterone on lipid profile in patients with chronic kidney disease and low testosterone level

Protocol summary

Study aim

Determining the therapeutic effect of testosterone on lipid profile in patients with chronic kidney disease

Design

single arm clinical trial

Settings and conduct

Patients attending to nephrology clinic will undergo fasting blood test for Total cholesterol, LDL, HDL, Triglycerid. 20 patients with low serum testosterone (less than 3.5 ng/ml) will take IM injection of Testosterone enanthate 100 mg every 2 weeks for 3 months. Then blood sampling will be repeated for lipid profile. All demographic and laboratory data will be recorded in each individual questionnaire.

Participants/Inclusion and exclusion criteria

40 to 60 years old Men suffering CKD with GFR less than 45 or ESRD and BMI between 35 to 40 without any pituitary disease, liver or thyroid dysfunction.

Intervention groups

IM injection of Testosterone enanthate 100 mg every 2 weeks for 3 months

Main outcome variables

Total cholesterol; LDL; HDL; Triglyceride

General information

Reason for update

Acronym

CKD

IRCT registration information

IRCT registration number: **IRCT20191009045044N1**

Registration date: **2019-12-26, 1398/10/05**

Registration timing: **retrospective**

Last update: **2019-12-26, 1398/10/05**

Update count: **0**

Registration date

2019-12-26, 1398/10/05

Registrant information

Name

Azadeh Kameli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 1238

Email address

a.kameli@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-07, 1398/06/16

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

2019-09-08, 1398/06/17

Actual recruitment end date

2019-10-09, 1398/07/17

Trial completion date

2020-01-20, 1398/10/30

Scientific title

The therapeutic effect of testosterone on lipid profile in patients with chronic kidney disease and low testosterone level

Public title

The therapeutic effect of testosterone on lipid profile in patients with chronic kidney disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

GFR less than 45 BMI 25 to 30 Male Gender Testosterone lower than 3.5 ng/lit

Exclusion criteria:

Any pituitary diseases Liver dysfunction Heart failure Any

thyroid disease Using any fat depressors Prostate cancer
Breast cancer BPH with obstruction

Age

From **40 years** old to **60 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

quasi experimental study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

NREC

Street address

No1. Daneshgah Blvd., Janbazan Sq., Ardabil town

City

Ardabil

Province

Ardabil

Postal code

5619813944

Approval date

2018-05-13, 1397/02/23

Ethics committee reference number

IR.ARUMS.REC.1398.316

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes

1

Description

Total Cholesterol

Timepoint

First of study and 3 months later

Method of measurement

Lab test

2

Description

Serum Triglyceride

Timepoint

First of study and 3 months later

Method of measurement

Lab test

3

Description

LDL Cholesterol

Timepoint

First of study and 3 months later

Method of measurement

Lab test

4

Description

HDL Cholesterol

Timepoint

First of study and 3 months later

Method of measurement

Lab test

Secondary outcomes

1

Description

Serum Testosterone

Timepoint

At the beginning of the study and three months later

Method of measurement

Lab test

Intervention groups

1

Description

Intervention group: IM injection of Testosterone enanthate 100, (each ampoule 1 ml contains Testosterone Enanthate 100 mg) every 2 weeks for 3 months. Each patient receives 6 injections.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital, Nephrology clinic

Full name of responsible person

Bahman Bashardoust

Street address

Noi'aghdam Ave.

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Ardabil

Province

Ardabil

Postal code

5619647531

Phone

+98 45 3325 1401

Email

b-bashardoust@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Ghodrat Akhavan Akbari

Street address

Daneshgah Ave.

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Email

research@arums.ac.ir

Web page address

<https://www.arums.ac.ir>

Grant name

research grant

Grant code / Reference number

129106

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

Yes

Title of funding source

Ardabil 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**

Ardabil University of Medical Sciences

Full name of responsible person

Azadeh Kameli

Position

Internal medicine resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Bahman Bashadoust

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Nephrology

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Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Azadeh Kameli

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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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

Confidentiality in medical profession

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