

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluating the effect of metformin on cyst volume and kidney volume in patients with Autosomal dominant polycystic kidney disease (ADPKD)

Protocol summary

Summary

This study is designed to evaluate the effect of metformin on the cyst and kidney volumes in patients with autosomal dominant poly-cystic kidney disease. During this study the patients will receive Metformin tablet 500mg (Rojin Daroo Company) once daily for one week and two tablets daily for second week and three tablets daily thereafter for 6 months. Serum creatinine level, glomerular filtration rate, 24-hour urinary protein, serum C-reactive protein (CRP) and interleukin 6 (IL-6), and kidney and cyst volumes using magnetic resonance imaging (MRI) will be assessed at the beginning and at the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013021912527N1**

Registration date: **2014-10-25, 1393/08/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-25, 1393/08/03

Registrant information

Name

Farrokhlegha Ahmadi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1568

Email address

ahmadifa@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2014-02-22, 1392/12/03

Expected recruitment end date

2014-10-30, 1393/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of metformin on cyst volume and kidney volume in patients with Autosomal dominant polycystic kidney disease (ADPKD)

Public title

Effect of metformin on the volume of cysts and kidneys in poly-cystic kidney disease patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Serum creatinine less than 1.4mg/dL at the beginning of the study; signing the informed consent form
Exclusion criteria: previous history of metformin use; allergy to metformin; any side effect during the intervention which prevents the patient from continuing the study

Age

From **14 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods-Keshavarz cross, Keshavarz Boulevard

City

Tehran

Postal code

Approval date

2014-02-22, 1392/12/03

Ethics committee reference number

19490

Health conditions studied

1

Description of health condition studied

Polycystic kidney disease

ICD-10 code

Q61.2

ICD-10 code description

Polycystic Kidney, autosomal dominant; Polycystic kidney adult type

Primary outcomes

1

Description

Volume of cyst

Timepoint

Before and after intervention

Method of measurement

MRI

2

Description

Kidney volume

Timepoint

Before and after intervention

Method of measurement

MRI

Secondary outcomes

1

Description

Serum creatinine

Timepoint

Before and after intervention

Method of measurement

Jaffe method

2

Description

24h-Urine protein

Timepoint

Before and after intervention

Method of measurement

Laboratory

3

Description

Serum IL-6

Timepoint

Before and after intervention

Method of measurement

kit

4

Description

Serum CRP

Timepoint

Before and after intervention

Method of measurement

Kit

5

Description

GFR

Timepoint

Before and after intervention

Method of measurement

Calculation

Intervention groups

1

Description

Patients will take 1 tablet of metformin 500 mg (Rogin Daroo Company) daily for the first week, two tablets

daily for the second week and three tablets daily thereafter up to six months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Farrokhlegha Ahmadi

Street address

Gharib Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Younesian

Street address

Keshavarz Boulevard

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

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

Name of organization / entity

Nephrology Research Center, Tehran University of Medical Sciences

Full name of responsible person

Dr. Farrokhlegha Ahmadi

Position

Nephrologist, Associate Professor

Other areas of specialty/work

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Dialysis ward, Imam Khomeini Hospital, Gharib Street

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Person responsible for scientific inquiries

Contact

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Nephrologist, Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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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