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 recieve Metformin tablet 500mg (Rojin Daroo Comapny) 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 assesed at the begining 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
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Iran (Islamic Republic of)
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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 Committe of Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Ghods-Keshavarz cross, Keshavarz Boulvard

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 Resaerch Center, Tehran University of Medical Sciences

Full name of responsible person

Dr. Farrokhlagha Ahmadi

Position

Nephrologist, Associate Proffessor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Name of organization / entity

Nephrology Research Center, Tehran University of Medical Sciences

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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