

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of metformin effect on progression of autosomal dominant polycystic kidney disease; a clinical trial

Protocol summary

Summary

1)objectives: evaluation of metformin effect on progression of autosomal dominant polycystic kidney disease. 2)Design: double blind randomized placebo controlled trial. 3)Setting and conduct: measurement of kidneys volume with MRI in 30 patients with autosomal dominant polycystic kidney disease in Firoozgar hospital, then prescription of drug or placebo for 6 months after random allocation to two groups, then measurement of kidneys volume again. 4)Participants: patients with diagnosis of autosomal dominant polycystic kidney disease. major eligibility criteria: age between 18-60 years old; glomerular filtration rate ≥ 60 cc/min. exclusion criteria: history of diabetes mellitus; history of congestive heart failure; history of liver failure. 5)Interventions: metformin or placebo. 6)main outcome measures: kidneys volume

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102111194N1**

Registration date: **2013-02-13, 1391/11/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-13, 1391/11/25

Registrant information

Name

Foroogh Sabzghabaei

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1600

Email address

f-sabzghabaei@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Science

Expected recruitment start date

2013-02-01, 1391/11/13

Expected recruitment end date

2014-02-01, 1392/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of metformin effect on progression of autosomal dominant polycystic kidney disease; a clinical trial

Public title

Evaluation of metformin effect on progression of autosomal dominant polycystic kidney disease; a clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: Known case of Autosomal dominant polycystic kidney disease (by sonography); age between 18-60 years old; GFR ≥ 60 cc/min. Exclusion: history of diabetes mellitus; history of heart failure; history of liver failure

Age

From **18 years** old to **60 years** old

Gender

Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
no

Secondary trial Id
no

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Tehran University of Medical Science

Street address
Ghods st., Keshavarz Blvd.

City
Tehran

Postal code

Approval date
2012-12-26, 1391/10/06

Ethics committee reference number
17059

Health conditions studied

1

Description of health condition studied
Autosomal Dominant Polycystic Kidney Disease

ICD-10 code
Q61.2

ICD-10 code description
Polycystic kidney, adult type

Primary outcomes

1

Description
kidneys volume

Timepoint
6 months

Method of measurement
Magnetic Resonance Imaging

Secondary outcomes

empty

Intervention groups

1

Description
Tablet Metformin 500 mg three times a day

Category
Treatment - Drugs

2

Description
Tablet placebo one tab three times a day

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Firoozgar Hospital

Full name of responsible person
Dr. Foroogh Sabzghabaei

Street address
Behafarin St., Karimkhan Zand Ave., Valiasr Sq.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for research, Tehran University of Medical Science

Full name of responsible person
Akbar Fotuhi M.D.

Street address
Ghods st., Keshavarz Blvd.

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 Science

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**

Tehran University of Medical Science

Full name of responsible person

Dr. Foroogh Sabzghabaei

Position

Nephrologist/ assistant professor

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Web page address**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