

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Study the role of dopamine receptors on the structure and function of endothelial primary cilia in vitro and in vivo

Protocol summary

Summary

In this trial we hypothesize that abnormal endothelial cilia in adult polycystic Kidney Disease (PKD) patients would have abnormal Nitric Oxide (NO) biosynthesis. Consequently, the trial objectives are the stimulation of ciliary dopamine receptor with dopaminergic agent (Levodopa) in PKD patients to: 1) restore NO biosynthesis and 2) correct their blood pressure. Inclusion criteria: adult type polycystic kidney disease with borderline hypertension; Control group inclusion criteria are essential borderline hypertension (HTN) without any secondary cause and are age-matched with PKD group. Exclusion criteria are: Pregnancy, lactation, diabetes mellitus, myocardial infarction, angina, arrhythmias, renal transplantation, renal failure, serum creatinin more than 3mg/dL, dialysis, sever hypertension, receiving antihypertensive drugs. Study population: Adult Polycystic Kidney Disease (PKD) Sample size: 30 patients The intervention drug is levodopa (as the metabolic precursor of dopamine) to stimulate ciliary dopamine receptor. Main outcome measures are serum nitric oxide and blood pressure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012110611384N1**

Registration date: **2012-12-03, 1391/09/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-03, 1391/09/13

Registrant information

Name

Sarmed Kathem

Name of organization / entity

College of Pharmacy-University of Baghdad

Country

Iraq

Phone

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Recruitment status

Recruitment complete

Funding source

College of Pharmacy-University of Baghdad

Expected recruitment start date

2012-06-01, 1391/03/12

Expected recruitment end date

2012-09-30, 1391/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the role of dopamine receptors on the structure and function of endothelial primary cilia in vitro and in vivo

Public title

Dopamine receptor in hypertension with Polycystic Kidney Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: adult type polycystic kidney disease with borderline hypertension; Control group inclusion criteria are essential borderline hypertension without any secondary cause. Exclusion criteria are: Pregnancy, lactation, diabetes mellitus, myocardial infarction,

angina, arrhythmias, renal transplantation, renal failure, serum creatinin more than 3mg/dL, dialysis, sever hypertension, recieving antihypertensive drugs.

Age

From **25 years** old to **45 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

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of College of Pharmacy- graduate study committee

Street address

Babalmouadhun 14026

City

Baghdad

Postal code

Approval date

2012-05-22, 1391/03/02

Ethics committee reference number

2684

Health conditions studied

1

Description of health condition studied

Adult Polycystic Kidney Disease

ICD-10 code

Q61.2

ICD-10 code description

Polycystic kidney, autosomal dominant Polycystic kidney, adult type

Primary outcomes

1

Description

Blood Pressure

Timepoint

0 hour, 2 hours, 7 days

Method of measurement

mercury sphygmomanometer

2

Description

Serum Nitric Oxide

Timepoint

0 hour, 7 days

Method of measurement

serum detection by Greiss reaction (colorimetric)

Secondary outcomes

1

Description

Heart rate

Timepoint

0 hour, 2 hour, 7 days

Method of measurement

radial pulse method

2

Description

Assymetric dimethylarginine

Timepoint

0 hour, 7 days

Method of measurement

serum samples by ELISA

3

Description

Serum Creatinin

Timepoint

0 hour, 7 days

Method of measurement

serum sample by ready made kit

4

Description

Urea

Timepoint

0 hour, 7 days

Method of measurement

serum sample by ready made kit

5

Description

calcium

Timepoint

0 hour, 7 days
Method of measurement
serum sample by ready made kit

6

Description
sodium
Timepoint
0 hour, 7 days
Method of measurement
serum sample by ready made kit

7

Description
Potassium
Timepoint
0 hour, 7 days
Method of measurement
serum sample by ready made kit

8

Description
Albumin
Timepoint
0 hour, 7 days
Method of measurement
serum sample by ready made kit

9

Description
Alanine Aminotransferase
Timepoint
0 hour, 7 days
Method of measurement
serum sample by ready made kit

10

Description
Aspartate Aminotransferase
Timepoint
0 hour, 7 days
Method of measurement
serum sample by ready made kit

11

Description
Alkaline Phosphatase
Timepoint
0 hour, 7 days
Method of measurement
serum sample by ready made kit

12

Description
Total Bilirubin
Timepoint
0 hour, 7 days

Method of measurement
serum sample by ready made kit

13

Description
Body Mass Index
Timepoint
baseline
Method of measurement
Weight (kg)/Height (square meter)

Intervention groups

1

Description
Levodopa 50 mg capsule three times daily for 7 days;
Domperidone 20 mg to reduce nausea used 30 minutes
before Levodopa dose for 7 days
Category
Treatment - Drugs

2

Description
Levodopa 100 mg capsule, three times daily for 7 days;
Domperidone 20 mg to reduce nausea used 30 minutes
before levodopa dose for 7 days
Category
Treatment - Drugs

3

Description
control, placebo capsule three times daily for 7 days;
domperidone 20 mg also used in this group to simulate
drug group
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alkadhumia Academic Hospital
Full name of responsible person
Dr Mohammed M. Alsaïdi
Street address
Alkadhumia, st. 60
City
Baghdad

2

Recruitment center
Name of recruitment center
Renal Diseases and Transplant Center
Full name of responsible person
Dr Qaïss H. Altaei

Street address

Medical City Complex, Babalmoadhun

City

Baghdad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

The Dean, College of Pharmacy, University of Baghdad

Full name of responsible person

Alaa A. Abdulrasool

Street address

Babalmoadhun 14026

City

Baghdad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

The Dean, College of Pharmacy, University of Baghdad

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**

College of Pharmacy-University of Baghdad; College of Pharmacy-University of Toledo

Full name of responsible person

Sarmed H. Kathem

Position

Faculty

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Province

Baghdad

Postal code**Phone**

009647901552609

Fax**Email****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