

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Determination of the effect of pentoxifylline on microalbuminuria in type 2 diabetic patients

#### Protocol summary

##### Study aim

Determination of the effect of pentoxifylline on microalbuminuria in patients with diabetic nephropathy

##### Design

Double-blind, randomized clinical trial with one control group

##### Settings and conduct

A double blind study on the effects of Pentoxifylline on microalbuminuria in diabetic type II patients that will take place in Imam Khomeini, Ahvaz, Khuzestan, Iran. Patients, the care provider and data gatherers are blinded.

##### Participants/Inclusion and exclusion criteria

Type 2 diabetic Outpatients aged 18-80 referred to the nephrology clinic of Imam Khomeini Hospital; Inclusion Criteria: Proteinuria more than 150mg/24hours; Microalbuminuria of more than 20 mg albumin excretion in 24 hour urine Exclusion Criteria: Patients Suffering from Diabetic Retinopathy; Hypersensitivity to pentoxifylline; Pregnancy; Heart failure with Ejection fraction less than 35%; Any acute or febrile illness one month before induction to study; Use of spironolactone; Use of Warfarin

##### Intervention groups

After being divided into two groups and baseline lab tests, patients are treated with medication for 12 weeks, depending on the group. Intervention group: In addition to medications for the underlying disease, patients in this group use pentoxifylline 400 mg (Farabi Co., Iran) once a day, after meals. Control group: In addition to the drugs used for the underlying disease, patients in this group use a placebo designed in Jundishapur School of Pharmacy, which is similar in appearance to Pentoxifylline 400 mg, once a day and after meal.

##### Main outcome variables

Albuminuria

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190107042264N3**

Registration date: **2020-12-16, 1399/09/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-12-16, 1399/09/26**

Update count: **0**

##### Registration date

2020-12-16, 1399/09/26

##### Registrant information

##### Name

Ehsan Hedayatinejad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3334 3368

##### Email address

hedayatee.e@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-21, 1399/09/01

##### Expected recruitment end date

2021-05-19, 1400/02/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Determination of the effect of pentoxifylline on microalbuminuria in type 2 diabetic patients

## Public title

The effect of pentoxifylline on diabetic microalbuminuria

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Type II Diabetic Patients Proteinuria more than 150mg/24hours Microalbuminuria of more than 20 mg albumin excretion in 24 hour urine

### Exclusion criteria:

Patients Suffering from Diabetic Retinopathy Hypersensitivity to pentoxifylline Pregnancy Heart failure with Ejection fraction less than 35% Any acute or febrile illness one month before induction to study Use of spironolactone Use of Warfarin

## Age

From **18 years** old to **80 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator

## Sample size

Target sample size: **58**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Using a Sequence Generator (freely available at [www.random.org](http://www.random.org)), A set of numbers from 1 to 58 was requested in two columns, the results were two columns of 29 Integers from one to 58, without repetition, which were used for division.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

After obtaining a series of unsorted random numbers from the website, this series of numbers is provided to the pharmacist by the statistical consultant to code the drugs. The pharmacist then sorts the drug and placebo in encoded packages. After the eligible patients are referred, the drugs are given to them in the order of referral. Patients, prescribing physicians, and data collectors are kept blind to the contents of the drug.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

##### Street address

Faculty of Medicine, Ahvaz Jundishapur University of Medical Sciences, Esfand Street, Golestan, Ahvaz, Iran

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

1579461357

#### Approval date

2020-11-04, 1399/08/14

#### Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.075

## Health conditions studied

### 1

#### Description of health condition studied

Albuminuria in patients with diabetes Mellitus type II

#### ICD-10 code

E08.2

#### ICD-10 code description

Diabetes mellitus due to underlying condition with kidney complications

## Primary outcomes

### 1

#### Description

Albuminuria

#### Timepoint

before intervention, 12 weeks after intervention

#### Method of measurement

24-hour urine collection

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients in this group, in addition to receiving treatment for the underlying disease that is not altered by the intervention, are treated with pentoxifylline 400 mg (Farabi Company; Iran) once a day, after meals. This treatment lasts for 12 weeks.

#### Category

Treatment - Drugs

## 2

### Description

Control group: Patients in this group, in addition to receiving treatment for the underlying disease that is not altered by the intervention, are treated with placebo (produced in the Faculty of Pharmacy of Ahvaz Jundishapur University) once a day, after meals. This treatment lasts for 12 weeks.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Imam Khomeini Teaching Hospital

**Full name of responsible person**

Shokouh Shayanpour

**Street address**

Imam Khomeini Hospital - Shahid Ahvazian Street - Azadegan Street

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6193673111

**Phone**

+98 61 3222 2114

**Email**

shayanpour-sh@ajums.ac.ir

**Web page address**

<https://himam.ajums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mehdi Ahmadi Moghadam

**Street address**

Central library, Ahvaz Jundishapur University of Medical Sciences, Esfand St, Golestan

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715794

**Phone**

+98 61 3373 8383

**Email**

ahmadi-m@ajums.ac.ir

**Grant name****Grant code / Reference number**

CRD-9908

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Shokouh Shayanpour

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Imam Khomeini Hospital - Shahid Ahvazian Street - Azadegan Street

**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

shayanpour-sh@ajums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Shokouh Shayanpour

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Shokouh Shayanpour  
**Position**  
Assistant professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Internal Medicine  
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shayanpour-sh@ajums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### 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