

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of adding Spironolactone to Enalapril therapy on micro albuminuria due to diabetes.

#### Protocol summary

##### Summary

The objective of the present study was to investigate the effect of addition of Spironolactone to Enalapril on urinary albumin loss in diabetic patients. A total of 60 diabetic patients with micro albuminuria due to DM type II, selected according to inclusion and exclusion criteria, were randomly assigned into the following 2 groups. During 3 months of the study, the patients of one group received only Enalapril, and those in the other group received both Spironolactone and Enalapril. Urine albumin and creatinine were measured, and albumin on creatinine ratio in urine samples calculated, and quantitative changes of albuminuria at the beginning of the study and after 3 months and compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201109067483N1**

Registration date: **2011-12-08, 1390/09/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-12-08, 1390/09/17

##### Registrant information

###### Name

Amirabbas Vaezi

###### Name of organization / entity

Metabolic Disease Research center

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 1336 0084

##### Email address

avaezi@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Qazvin University of Medical Sciences

##### Expected recruitment start date

2010-11-22, 1389/09/01

##### Expected recruitment end date

2011-09-21, 1390/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of adding Spironolactone to Enalapril therapy on micro albuminuria due to diabetes.

##### Public title

The effect of addition of Spironolactone to Enalapril on urinary albumin loss in diabetic patients.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Diabetic nephropathy as micro-albuminuria, More than 18 years old, Less than 80 years old  
Exclusion criteria: Serum creatinine more than 2mg/dl, Serum Potassium more than 5.5 mmol/dl at any stage of the study, Cardiac ejection fraction less than 35%

##### Age

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

##### Gender

Both

##### Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research deputy of Qazvin University of Medical Sciences

##### Street address

Shahid Bahonar Ave. , Qazvin University of Medical Sciences

##### City

Qazvin

##### Postal code

#### Approval date

2011-04-27, 1390/02/07

#### Ethics committee reference number

4417/20/28

## Health conditions studied

### 1

#### Description of health condition studied

Proteinuria due to diabetic nephropathy in diabetes type 2

#### ICD-10 code

E11

#### ICD-10 code description

Non-insulin dependent diabetes mellitus

## Primary outcomes

### 1

#### Description

Urine Albumin

#### Timepoint

at the beginning and the end of the study

#### Method of measurement

by laboratory kit

### 2

#### Description

Urine Creatinine

#### Timepoint

at the beginning and the end of the study

#### Method of measurement

by laboratory kit

### 3

#### Description

Albumin on creatinine ratio

#### Timepoint

at the beginning and the end of the study

#### Method of measurement

by division of numeric amount of albumin on numeric amount of creatinine

## Secondary outcomes

### 1

#### Description

Systolic blood pressure

#### Timepoint

At the beginning , after the 6th week and at the end of the study.

#### Method of measurement

by sphygmomanometer (mmHg)

### 2

#### Description

Serum potassium

#### Timepoint

At the beginning , after the 6th week and at the end of the study.

#### Method of measurement

by laboratory kit (mmol/dl)

### 3

#### Description

Glumerular filtration ration (GFR)

#### Timepoint

at the beginning and the end of the study

#### Method of measurement

by MDRD method (Modification of Diet in Renal Disease)

### 4

#### Description

body weight

#### Timepoint

at the beginning and the end of the study

#### Method of measurement

medical weighing scale(Kg)

### 5

#### Description

Diastolic blood pressure

**Timepoint**

At the beginning , after the 6th week and at the end of the study.

**Method of measurement**

Sphygmomanometer (mmHg)

**Intervention groups****1****Description**

Enalapril, 25 mg pr os twice a day, to half of the patients.

**Category**

Treatment - Drugs

**2****Description**

Enalapril, 25 mg pr os twice a day and Spironolacton, 25 mg, per os, once a day, to half of the patients.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Specialty Clinic of Bou Ali Sina university Hospital, Qazvin

**Full name of responsible person**

Dr. Amir Abbas Vaezi

**Street address**

Bou Ali Sina university hospital, Bou Ali Sina St.

**City**

Qazvin

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

Qazvin Metabolic Diseases Research Centre(QMDRC), Qazvin university of medical sciences

**Full name of responsible person**

Dr. Amir Abbas Vaezi

**Street address**

Bou Ali Sina university hospital, Bou Ali Sina St.

**City**

Qazvin

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

Yes

**Title of funding source**

Qazvin Metabolic Diseases Research Centre(QMDRC), Qazvin 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**

Qazvin university of medical sciences

**Full name of responsible person**

Dr. Amir Abbas Vaezi

**Position**

resident of internal medicine/MD

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Dr. Amir Abbas Vaezi

**Position**

Resident of internal medicine/MD

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Qazvin Metabolic Diseases Research Centre(QMDRC),  
Qazvin university of medical sciences

**Full name of responsible person**

Dr. Amir Abbas Vaezi

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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*