Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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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 filteration 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
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Position
resident of internal medicine/MD
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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