Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Anti Micro Albuminuric Effect of Spironolatone with or without Losartan in Diabetic type II Patients

Protocol summary

Summary

This study will do in 35-75 years old diabetic patient with microalbuminuria. Exclusion criteria: 1) systolic blood pressure > 180mmHg; 2)Diastolic blood pressure > 110mmHg; 3)Serum k > 5.5 mg/dl; 4)CVA or MI in 6 month ago; 5)Treatment whit corticosteroids, NSAIDs, immunosuppressive; 6)Patients whit renovascular disease, obstructive uropathy, collagenous disease, malignancy, alcohol users, addiction; 7)Pregnant or breast fed women; 8)HbA1C > 8%. Sample is 60 persons that will study for 12 weeks. The patients will be divided in 2 groups: First group intake spironolactone 25mg daily plus placebo ½ tablet twice daily; Second group intake spironolactone 25mg daily whit plus losartan 12.5mg twice daily. Blood pressure, Na, K, urea, Cr, will be checked every 4weeks. Microalbuminuria will be measured in the beginning and end of study. We expect microalbuminuria will improve or decrease less than half after 12 weeks treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138806211241N2**
Registration date: **2012-01-18, 1390/10/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-01-18, 1390/10/28

Registrant information

Name

Atieh Makhlough

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2009-10-23, 1388/08/01

Expected recruitment end date

2010-03-21, 1389/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Anti Micro Albuminuric Effect of Spironolatone with or without Losartan in Diabetic type II Patients

Public title

Anti Micro Albuminuric Effect of Spironolatone with or without Losartan in Diabetic type II Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: This study will done in 35-75 years old diabetic patient with microalbuminuria. Exclusion criteria: 1)systolic blood pressure > 180mmHg; 2)Diastolic blood pressure > 110mmHg; 3)Serum k > 5.5 mg/dl; 4)CVA or MI in 6 month ago; 5)Treatment whit corticosteroids, NSAIDs, immunosuppressive; 6)Patients whit renovascular disease, obstructive uropathy, collagenous disease, Malignancy, alcohol users, addiction; 7)Pregnant or breast fed women; 8)HbA1C >

8%.

Age
From **35 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mazandaran University of Medical Sciences

Street address
No.2 Building Mazandaran University of Medical Sciences, Moallem Square

City
Sari

Postal code

Approval date
2010-09-30, 1389/07/08

Ethics committee reference number
88-89

Health conditions studied

1

Description of health condition studied
micrialbuminuria in diabetic type 2

ICD-10 code
N08.3

ICD-10 code description
Glomerular disorders in diabetes mellitus

Primary outcomes

1

Description
Measurement of urinary microalbuminuria

Timepoint
Before treatment and 12 weeks after treatment

Method of measurement
Laboratory

Secondary outcomes

1

Description
Measurement of sodium

Timepoint
Before treatment, 4, 8 and 12 weeks after treatment

Method of measurement
Lablatory

2

Description
Potassium

Timepoint
Before treatment, 4, 8 and 12 weeks after treatment

Method of measurement
Laboratory

3

Description
Creatinine

Timepoint
Before treatment, 4, 8 and 12 weeks after treatment

Method of measurement
Lablatory

4

Description
Urea

Timepoint
Before treatment, 4, 8 and 12 weeks after treatment

Method of measurement
Lablatory

5

Description
Hypertension

Timepoint
Before treatment, 4, 8 and 12 weeks after treatment

Method of measurement
The barometer

Intervention groups

1

Description
Intervention groups: spironolactone 25 mg daily plus losartan 12.5 twice daily

Category
Treatment - Drugs

2

Description
Control group: spironolactone 25 mg with placebo half tablet twice daily
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr Atieh Makhlough
Street address
Clinic of Nephrology and Diabetes, Imam Khomeini Hospital, Razi Avenue
City
Sari

2

Recruitment center
Name of recruitment center
Tooba Clinic
Full name of responsible person
Dr Atieh Makhlough
Street address
Tuba specialist clinic, Caspian Boulevard
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Ahmadali Enayati
Street address
No.2 Building, Mazandaran University of Medical Sciences, Moallem Square
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Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Atieh Makhlough
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Person responsible for updating data

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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