

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Anti Micro Albuminuric Effect of Spironolactone 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 Makhloogh

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 Spironolactone with or without Losartan in Diabetic type II Patients

Public title

Anti Micro Albuminuric Effect of Spironolactone 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 Makhloogh

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 Makhloogh

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

City

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

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Full name of responsible person

Dr Atieh Makhloogh

Position

Nephrologist/Associate Professor

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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