

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effects of hydrochlorothiazide and spironolactone in reducing of proteinuria in patients with diabetic nephropathy treated by angiotensin converting enzyme inhibitors

Protocol summary

Summary

This study aim to evaluate the effects of hydrochlorothiazide and spironolactone in reducing of proteinuria in patients with diabetic nephropathy treated by angiotensin converting enzyme inhibitors. 90 diabetic patients that were treated with angiotensin converting enzyme inhibitors because of proteinuria and hypertension in Sheikh-el-Raeis clinic will randomly be selected and divided in two groups with 45 members which have same age, gender, proteinuria and GFR. the first group will receive Spironolactone 25 mg/day and the other one Hydrochlorothiazide 25 mg/day. the range of proteinuria, blood pressure, serum urea, creatinin, sodium, potassium and albumin before and 3 month after study will be measured in both groups.

General information

Acronym

TDNS

IRCT registration information

IRCT registration number: **IRCT201408083742N2**

Registration date: **2014-10-15, 1393/07/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-15, 1393/07/23

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of hydrochlorothiazide and spironolactone in reducing of proteinuria in patients with diabetic nephropathy treated by angiotensin converting enzyme inhibitors

Public title

Effects of hydrochlorothiazide and spironolactone in treatment of kidney involvement in diabetic patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: blood pressure>130/80 under treatment with ACEIs; proteinuria>150 mg/24hr

Exclusion criteria: serum potassium>5 meq/L; GFR<30 ml/min; proteinuria due to other conditions such as UTI or CHF

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz University of Medical Sciences

Street address

Tabriz, Golgasht street, Tabriz University of Medical Sciences

City

Tabriz

Postal code

51665118

Approval date

2014-07-06, 1393/04/15

Ethics committee reference number

9354

Health conditions studied**1****Description of health condition studied**

diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

proteinuria

Timepoint

before and 3 month after study

Method of measurement

24 hr urine collection

Secondary outcomes**1****Description**

blood pressure

Timepoint

before and 1 week and 1 and 3 month after study

Method of measurement

barometer(mmHg)

2**Description**

serum potassium

Timepoint

before and 1 week and 1 and 3 month after study

Method of measurement

biochemical test(meq/L)

3**Description**

serum sodium

Timepoint

before and 3 month after study

Method of measurement

biochemical test(meq/L)

4**Description**

serum creatinin

Timepoint

before and 3 month after study

Method of measurement

biochemical test(mgr/dl)

5**Description**

serum urea

Timepoint

before and 3 month after study

Method of measurement

biochemical test(mgr/dl)

6**Description**

serum albumin

Timepoint

before and 3 month after study

Method of measurement

biochemical test(gr/dl)

7**Description**

24hr urine volume

Timepoint

before and 3 month after study

Method of measurement

biochemical test(mililiter)

8

Description

24hr urine creatinin

Timepoint

before and 3 month after study

Method of measurement

biochemical test(miligram)

9

Description

albumin/creatinin ratio

Timepoint

before and 3 month after study

Method of measurement

biochemical test

10

Description

glomerular filtration

Timepoint

before and 3 month after study

Method of measurement

Cockcroft-Gault equation

Intervention groups

1

Description

First group: Spironolactone 25 mg daily for 3 month

Category

Treatment - Drugs

2

Description

Second group: Hydrochlorthiazide 25 mg daily for 3 month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheikh el Raeis clinic

Full name of responsible person

Taher manzary MD

Street address

Azadi avenue, Golgasht street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Medical Faculty

Full name of responsible person

Hasan Soleimanpour MD

Street address

Medical faculty, Golgasht street

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Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research deputy of Medical Faculty

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Taher Manzary

Position

Internal medicine assistant

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Web page address**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