Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

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

Protocol summary

Summary
This study aim to evaluate the effects of hydrochlorthiazide and spironolactone in reducing of proteinuria in patients with diabetic nephropathy treated by angiotensin coverting enzyme inhibitors. 90 diabetic patients that were treated with angiotensin coverting enzyme inhibitors because of proteinuria and hypertension in Sheikh-el-Raeis clinic will randomly be selected and devided 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 Hydrochlirthiazide 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
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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 hydrochlorthiazide and spironolactone in reducing of proteinuria in patients with diabetic nephropathy treated by angiotensin coverting enzyme inhibitors

Public title
Effects of hydrochlorthiazide and spironolactone in tratement 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 potasium>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 potasium
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 cratinin
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

glumerolar 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

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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

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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