Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effects of Losartan with combination of Losartan and pyridoxamine on proteinuria in type 2 diabetic patients

Protocol summary

Summary

Our aim in this study is comparison of two treatment regimens in reduction of proteinuria in type 2 diabetic patients. In a randomized unicentral trial 44 patients with type two diabetes from both genders and referring to the nephrology clinic of Emam Reza hospital, Tabriz, Iran were assigned in 2 equal-sized groups to receive oral losartan 25 mg BID or losrtan with the same dose together with pyridoxamine 25 mg/day. The key inclusion criteria were to be 18 to 70 years old; to have type 2 diabetes; 24 hours urine albumin more than 300 mg/dl or to have a albumin to creatinine ratio of more than 30. The key exclusion criteria were to have a history of diabetic ketoacidosis; and to have a history of sensitivity to the Vitamin B group drugs. Renal function status based on serum creatinine, urea, sodium, potassium, triglyceride, cholesterol and uric acid together with urine creatinine and 24 hours urine albumin and protein before and after treatment will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012121311743N1**
Registration date: **2012-12-31, 1391/10/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-12-31, 1391/10/11

Registrant information

Name

Kamaleddin Golbazi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-12-09, 1391/09/19

Expected recruitment end date

2013-06-08, 1392/03/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Losartan with combination of Losartan and pyridoxamine on proteinuria in type 2 diabetic patients

Public title

Comparison of two treatment regimens in reduction of proteinuria in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (to be 18 to 70 years old; to have type 2 diabetes; 24 hours urine albumin more than 300 mg/dl or to have a albumin to creatinine ratio of more than 30; not to have a nephropathy due to other diseases)
Exclusion criteria: (patients with advanced cardiac or cerebral diseases; to have a history of diabetic ketoacidosis and to have a history of sensitivity to the

Vitamin B group drugs)

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

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

Ethics Committee of Tabriz University of Medical Sciences

Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Square

City

Tabriz

Postal code

Approval date

2012-12-08, 1391/09/18

Ethics committee reference number

91156

Health conditions studied

1

Description of health condition studied

Diabetic nephropathy

ICD-10 code

N08.3*

ICD-10 code description

Glomerular disorders in diabetes mellitus

Primary outcomes

1

Description

Serum creatinine level

Timepoint

Before and after treatment

Method of measurement

Lab

2

Description

Serum sodium level

Timepoint

before and after treatment

Method of measurement

Lab

3

Description

Serum potassium level

Timepoint

before and after treatment

Method of measurement

Lab

4

Description

Serum urea level

Timepoint

before and after treatment

Method of measurement

Lab

5

Description

Serum cholesterol level

Timepoint

before and after treatment

Method of measurement

Lab

6

Description

Serum uric acid level

Timepoint

before and after treatment

Method of measurement

Lab

7

Description

serum triglyceride level

Timepoint

before and after treatment

Method of measurement

Lab

8

Description
Urine creatinine level
Timepoint
before and after treatment
Method of measurement
Lab

9

Description
24 hours urine albumin level
Timepoint
before and after treatment
Method of measurement
Lab

10

Description
24 hours urine protein level
Timepoint
before and after treatment
Method of measurement
Lab

Secondary outcomes

empty

Intervention groups

1

Description
For group Losartan: Losartan 25 mg tablets will be administered two times a day for 2 months.
Category
Treatment - Drugs

2

Description
For group Losartan plus pyridoxamine: Losartan tablets 25 mg two times a day together with Pyridoxamine tablets 25 mg once a day will be administered for 2 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Nephrology clinic of Emam Reza hospital
Full name of responsible person
Seyyed Sadreddin Hashemi Rasi
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Alireza Ostad Rahimi
Street address
Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah square
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
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Kamaleddin Golbazi
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Resident of internal diseases
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Web page address

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