

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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

Tariz University of Medical Sciences

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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

Full name of responsible person

Kamaleddin Golbazi

Position

Resident of internal diseases

Other areas of specialty/work

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Internal diseases ward, Imam Reza hospital, Golgasht st.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Kamaleddin Golbazi

Position

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Fax**Email**

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Hemmati

Position

General physician

Other areas of specialty/work**Street address****City****Postal code****Phone****Fax****Email**

mehdi.hemmati@rocketmail.com

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