

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of three (enalapril , lozar , metoral) and two (enalapril , lozar) drugs inhibition of Renin-Angiotensin-Aldosterone System (RAAS) in treatment of diabetic nephropathy

Protocol summary

Summary

According to the clinical guidelines on chronic kidney disease with hypertension, combination therapy with multiple renin-angiotensin-aldosterone system (RAAS) blockers has been recommended as standard first-line therapy. To date, dual and triple blockade of the RAAS has been evaluated by several investigators. This study aims comparing three (Enalapril, Losartan, Metoral) and two (Enalapril , Losatan) directional inhibitions of RAAS in treatment of diabetic nephropathy. Methods & Materials: 103 diabetic patients without ESRD were recruited in Tabriz Sina Hospital during a one-year period. The patients randomized in two groups: group A received triple blockade of RAAS with ACEI+ARB+ β blocker and group B received dual blockade with ACEI+ARB (and placebo). Basal and post treatment parameters (after six months) including blood pressure, urine albumin, serum BUN, Cr, Na, K and HbA1C and GFR were compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901293742N1**
Registration date: **2010-05-29, 1389/03/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-05-29, 1389/03/08

Registrant information

Name

Hamid Noshad

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz university of medical sciences

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2011-04-26, 1390/02/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of three (enalapril , lozar , metoral) and two (enalapril , lozar) drugs inhibition of Renin-Angiotensin-Aldosterone System (RAAS) in treatment of diabetic nephropathy

Public title

Three and two drugs inhibition of Renin-Angiotensin-Aldosterone System (RAAS) in treatment of diabetic nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: proteinuria, impaired renal function in diabetic patients. Exclusion criteria: pregnancy, milking, drug allergy, bilateral renal artery stenosis, ESRD, beta

blocker contraindication, patient rejection.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **103**

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**

Tabriz university of medical sciences

Street address

Tabriz university of medical sciences

City

Tabriz

Postal code

5138638779

Approval date

2010-03-15, 1388/12/24

Ethics committee reference number

8819

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**

proteinuria

Timepoint

one month

Method of measurement

urine exam

2**Description**

kidney function

Timepoint

one month

Method of measurement

urine and blood exam

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

blood pressure

Timepoint

one month

Method of measurement

blood pressure measurment by sphygmomonometere

2**Description**

Blood potassum

Timepoint

one month

Method of measurement

Blood Biochemistery

3**Description**

HgA1c

Timepoint

one month

Method of measurement

Blood biochemistery

4**Description**

Na

Timepoint

one month

Method of measurement

Blood biochemistery

Intervention groups**1****Description**

Case:enalapril 5mg bid,lozar 25mg bid,metoral 50mg bid

Category

Treatment - Drugs

2

Description

contol:enalapril 5 mg bid,lozar 25 mg bid.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Dr.Hamid Noshad

Street address

Sina hospital

City

Tabriz

2

Recruitment center

Name of recruitment center

Sheikholraeis clinic

Full name of responsible person

Dr.Hamid Noshad

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz university of medical sciences

Full name of responsible person

Dr.Ostad Rahimi

Street address

Tabriz university of medical sciences

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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Position

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Other areas of specialty/work

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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