

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 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+ $\beta$  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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1541 5023

##### Email address

noshadh@tbzmed.ac.ir

##### 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 measurement by sphygmomanometer

**2****Description**

Blood potassium

**Timepoint**

one month

**Method of measurement**

Blood Biochemistry

**3****Description**

HgA1c

**Timepoint**

one month

**Method of measurement**

Blood biochemistry

**4****Description**

Na

**Timepoint**

one month

**Method of measurement**

Blood biochemistry

**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

**Full name of responsible person**

Dr.Hamid Noshad

**Position**

Nephrologist

**Other areas of specialty/work**

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**Position**

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**Other areas of specialty/work**

**Street address**

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**Phone**  
**Fax**  
**Email**  
**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*