

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing administrating ARBs Vs ARB plus N-acetyl cysteine on reducing proteinuria in the patients suffering from type-II diabetes mellitus

#### Protocol summary

##### Summary

We will investigate the renoprotective efficacy of angiotensin receptor blocker and N-cetyl cystein in prevention or reduction of proteinuria in patients with diabetic nephropathy. In this randomized clinical trial, 70 patients with diabetes type II suffering from renal dysfunction induced proteinuria with serum creatinine more than 1.8mg and urine protein in urinalysis will be recruited. The patients are randomly assigned into intervention or conrol group to receive Angiotensin Receptor Blockers (25mg, twice daily) as well as N-acetylcysteine (600mg, twice daily) or only Angiotensin Receptor Blockers (25 mg twice daily), respectively, for two months. Urine protein will be checked before and two month after the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201104046123N1**

Registration date: **2011-04-19, 1390/01/30**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-04-19, 1390/01/30

##### Registrant information

##### Name

Seyed Sadraddin Rasi Hashemi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1337 3966

##### Email address

rasihashemis@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2011-03-22, 1390/01/02

##### Expected recruitment end date

2011-06-23, 1390/04/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing administrating ARBs Vs ARB plus N-acetyl cysteine on reducing proteinuria in the patients suffering from type-II diabetes mellitus

##### Public title

Prevention and treatment of proteinuria in diabetic nephropathy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: willing to participate, no underlying malignancy, creatinin more than 1.8 Exclusion criteria: no any other diseases

##### Age

From **25 years** old to **100 years** old

##### Gender

Both

##### Phase

**Groups that have been masked***No information***Sample size**Target sample size: **70****Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single 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****Approval date**

2010-11-08, 1389/08/17

**Ethics committee reference number**

7737/4/5

**Health conditions studied****1****Description of health condition studied**

Diabetic nephropathy

**ICD-10 code**

E10, E11,

**ICD-10 code description**

Glomerular disorder in diabetes mellitus

**Primary outcomes****1****Description**

Proteinuria.

**Timepoint**

before intervention and two monthS after treatment

**Method of measurement**

Urine collection in 24 hrs

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

Hemoglobin A1C

**Timepoint**

Before intervention and two months after treatment

**Method of measurement**

taking blood sample

**2****Description**

Blood suger

**Timepoint**

Before intervention and two months after treatment

**Method of measurement**

take blood sample

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

Intervention group: N-acetylcysteine 600mg twice daily as well as Losartan 25mg twice daily for two months

**Category**

Treatment - Drugs

**2****Description**

In control group: Losartan 25 mg twice in day for two month.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Emam Reza hospital, Sina Hospital, Sheikhol Raeis Clinics

**Full name of responsible person**

Dr. Sadreddin Rasi Hashemi

**Street address**

Nephrology ward, Emam reza Hospital, Tabriz Univesity of Medical Sciences

**City**

Tabriz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Sadreddin Rasi Hashemi

**Street address**

Emam Reza Hospital, 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. Sadreddin Rasi Hashemi

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

Nephrology ward, Emam reza Hospital, Tabriz University of Medical Sciences

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1334 7054

**Fax**

+98 41 1335 2073

**Email**

rasihashemis@tbzmed.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Sadreddin Rasi Hashemi

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

Nephrology ward, Emam reza Hospital, Tabriz University of Medical Sciences

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1334 7054

**Fax**

**Email**

rasihashemis@tbzmed.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

**Full name of responsible person**

Dr. Sadreddin Rasi Hashemi

**Position**

**Other areas of specialty/work**

**Street address**

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**Postal code**

**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*