Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

3

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-acetylcyctein 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

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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

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Person responsible for scientific inquiries

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Assistant Professsor

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Position

Other areas of specialty/work

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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