

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Survey of thiamin efficacy on proteinuria in diabetic nephropathy

Protocol summary

Summary

In this study, in the period of three months 80 patients with diabetic nephropathy that have inclusion criteria will be compared. Inclusion criteria including: all patients with diabetic nephropathy who have macroalbuminuria (proteinuria more than 300 mg/24h); more than 18 years old; HbA1c less than 12%. Exclusion criteria including: patient who reject usage of determinate dose of studying drug. In case group 24 hours before study proteinuria, Urea, Cr, lipid profile measured, then patient will be randomized. Randomized patients divided into Case and Control groups. Cases treated with thiamine 300mg/day for three months and after three months changes in 24 hours proteinuria studied. Then conclusions compared with control group who receive standard drug in this period of time. Also B.S, lipid profile and kidney function tests measured before and after of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105302858N3**

Registration date: **2011-07-08, 1390/04/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-07-08, 1390/04/17

Registrant information

Name

Hamid Taieby Khosroshahy

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1337 3966

Email address

khosroshahy@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University Of Medical Sciences and Health Services

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-07-23, 1390/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of thiamin efficacy on proteinuria in diabetic nephropathy

Public title

Survey of thiamin efficacy on urine protein level in diabetic patients with kidney involvement

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria including: all patients with diabetic nephropathy who have macroalbuminuria (proteinuria more than 300 mg/24h); more than 18 years old; HbA1c less than 12%. Exclusion criteria including: patient who reject usage of determinate dose of studying drug.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University Of Medical Siences and Health Services

Street address

Tabriz University Of Medical Siences and Health Services
Golgasht Ave .Tabiz East Azaraijan
Iran, Islamic Republic Of

City

Tabiz

Postal code

Approval date

2011-01-12, 1389/10/22

Ethics committee reference number

8417/4/5

Health conditions studied

1

Description of health condition studied

Proteihuria in diabetic nephropathy

ICD-10 code

E10-E14+

ICD-10 code description

Glomerular disorders in diabetes mellitus

Primary outcomes

1

Description

Changes in urine protein level

Timepoint

Three months after intervention

Method of measurement

Measurment of urine protein level

Secondary outcomes

1

Description

Serum HbA1C Level

Timepoint

Three monthes after intervention

Method of measurement

Plasma level measurment

2

Description

Lipd profil, HbA1C level

Timepoint

Three monthes after intervention

Method of measurement

Measurment of them in plasma

Intervention groups

1

Description

In control groap we use the standard treatment

Category

Treatment - Drugs

2

Description

For cases 300mg/day Thiamin for three monthes and for controles standard treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran, Islamic Republic Of , Tabriz Imam Reza Hospital

Full name of responsible person

Dr. Negar Sheikhdavodi Rezident Of Internal Medicine

Street address

Imam Reza Hospital, Golgasht Ave, Tabiz

City

Tabiz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University Of Medical Siences and Health Services

Full name of responsible person

Miss Maghami

Street address

Tabriz University Of Medical Sciences ,Golgashat Ave
,Tabriz

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 and Health Services

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 and Health Services

Full name of responsible person

Dr.Negar Sheikhdavodi

Position

Resident Of Internal Medicine

Other areas of specialty/work

Street address

Tabriz University Of Medical Sciences and Health ServicesGolgashat Ave .Tabriz

City

Tabriz

Postal code

Phone

+98 41 1334 1317

Fax

+98 41 1334 1317

Email

Soroushm@tbzmed.ac.ir

Web page address

www.tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University Of Medical Sciences and Health Services

Full name of responsible person

Dr.Hamid Taieby Khosroshahyh

Position

Associate Professor Of Nephrology

Other areas of specialty/work

Street address

Tabriz University Of Medical Sciences and Health ServicesGolgashat Ave .Tabriz

City

Tabriz

Postal code

Phone

+98 41 1334 1317

Fax

+98 41 1334 1317

Email

Khosroshahyh@tbzmed.ac.ir

Web page address

www.tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University Of Medical Sciences and Health Services

Full name of responsible person

Dr.Negar Sheikhdavodi

Position

Resident Of Internal Medicine

Other areas of specialty/work

Street address

Tabriz University Of Medical Sciences and Health Services Golgashat Ave .Tabriz

City

Tabriz

Postal code

Phone

+98 41 1334 1317

Fax

+98 41 1334 1317

Email

Soroushm@tbzmed.ac.ir

Web page address

WWW.tbzmed.ac.ir

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