

# 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 Sciences and Health Services

##### Street address

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

##### City

Tabriz

##### 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

Proteinuria 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

Measurement of urine protein level

## Secondary outcomes

### 1

#### Description

Serum HbA1C Level

#### Timepoint

Three months after intervention

#### Method of measurement

Plasma level measurement

### 2

#### Description

Lipid profile, HbA1C level

#### Timepoint

Three months after intervention

#### Method of measurement

Measurement of them in plasma

## Intervention groups

### 1

#### Description

In control group we use the standard treatment

#### Category

Treatment - Drugs

### 2

#### Description

For cases 300mg/day Thiamin for three months and for controls 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 Resident Of Internal Medicine

##### Street address

Imam Reza Hospital, Golgasht Ave, Tabriz

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University Of Medical Sciences and Health Services

##### Full name of responsible person

Miss Maghami

##### Street address

Tabriz University Of Medical Sciences ,Golgasht 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

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**Name of organization / entity**

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Dr.Hamid Taieby Khosroshahyh

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Associate Professor Of Nephrology

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**Name of organization / entity**

Tabriz University Of Medical Sciences and Health Services

**Full name of responsible person**

Dr.Negar Sheikhdavodi

**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