

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### A clinical trial to evaluate the effects of diet enriched with indigestible/fermentable complex carbohydrates on inflammatory markers in chronic hemodialysis patients.

#### Protocol summary

##### Summary

The main purpose of this study is to investigate the effect of high resistant starch diet in attenuation of chronic kidney disease (CKD) progression. For this purpose, 50 patients with CKD who are on chronic hemodialysis for more than 6 months and have inclusion criteria are selected. These patients are divided into two groups ( treatment and control). There was no randomization process. The treatment patients fed 20g diets supplemente with high fermentable fiber (amylose maize resistant starch, HAM-RS2) as a cakes and/or biscuits for 2 months, three times each day. The control patients received same cakes and/ or biscuits without high fermentable fiber. Diabetic patients, patients who have active infectious, inflammatory diseases and less than 18 years old were excluded from study. Finally, the impact of HAM-RS2 in inflammatory markers of CKD patients will be studied.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016062628644N1**  
Registration date: **2017-04-25, 1396/02/05**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-04-25, 1396/02/05

##### Registrant information

##### Name

Behzad Abedi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 5264 6224

##### Email address

abedib@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences.

##### Expected recruitment start date

2016-10-25, 1395/08/04

##### Expected recruitment end date

2017-04-25, 1396/02/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A clinical trial to evaluate the effects of diet enriched with indigestible/fermentable complex carbohydrates on inflammatory markers in chronic hemodialysis patients.

##### Public title

Effects of diet enriched with indigestible complex starch on chronic hemodialysis patients.

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Chronic kidney disease patients who are on chronic hemodialysis for more than 6 months.  
Exclusion criteria: Diabetic patients; Patients who have active infection; Patients who have inflammatory diseases; Patients who are under 18 years old.

## Age

From **40 years** old to **75 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

There was no randomization process.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences (TUOMS).

##### Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Golqasht Street, Tabriz.

##### City

Tabriz

##### Postal code

5166614733

#### Approval date

2017-02-16, 1395/11/28

#### Ethics committee reference number

IR.tbzmed.rec.1395.1286

## Health conditions studied

### 1

#### Description of health condition studied

Chronic kidney disease, stage 5

#### ICD-10 code

N18.5

#### ICD-10 code description

Chronic kidney disease, stage 5

## Primary outcomes

### 1

#### Description

High-density lipoprotein (HDL)

#### Timepoint

8 weeks following end of treatment.

#### Method of measurement

Sampling from blood, urine and fecal of patients.

### 2

#### Description

Interleukin (IL)-1b

#### Timepoint

8 weeks following end of treatment

#### Method of measurement

Sampling from blood, urine and fecal of patients.

### 3

#### Description

Interleukin (IL)-6

#### Timepoint

8 weeks following end of treatment

#### Method of measurement

Sampling from blood, urine and fecal of patients.

## Secondary outcomes

### 1

#### Description

-

#### Timepoint

-

#### Method of measurement

-

## Intervention groups

### 1

#### Description

Intervention group: patients in this group will receive cakes or biscuits made with starch of high amylose, 20 gram in each day, for 2 months.

#### Category

Prevention

### 2

#### Description

Control group: patients in this group will receive cakes or biscuits without starch of high amylose content each day, for 2 months.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

29 Bahman hospital.

**Full name of responsible person**

Hamid Tayebi Khosroshahi

**Street address**

29 Bahman hospital, Shahryar Blvd, Imam street, Tabriz.

**City**

Tabriz

**Street address**

School of Advanced Medical Science, Tabriz University of Medical Sciences, University Street, Golqasht street, Tabriz.

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**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Tabriz University of Medical Sciences

**Full name of responsible person**

Hamid Tayebi Khosroshahi

**Street address**

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Golqasht street, Tabriz.

**City**

Tabriz

**Grant name****Grant code / Reference number**

-

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of 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; Tabriz-Iran

**Full name of responsible person**

Behzad Abedi

**Position**

Student

**Other areas of specialty/work**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hamid Tayebi Khosroshahi

**Position**

Professor

**Other areas of specialty/work****Street address**

Kidney research center, Tabriz University of Medical Sciences, University street, Golqasht street, Tabriz.

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Behzad Abedi

**Position**

Student

**Other areas of specialty/work****Street address**

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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*