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 inflamatory 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
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Behzad Abedi
Name of organization / entity
Tabriz University of Medical Sciences
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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

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

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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

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Professor

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Person responsible for updating data

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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