

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of fenugreek seeds consumption on metabolic status, serum adiponectin, Hs-CRP & ICAM-1 (Intercellular Adhesion Molecule-1) levels in type 2 diabetic patients

Protocol summary

Summary

In this study, patients were referred to an endocrinologist with Objective of Determination the Effects of fenugreek seeds consumption on metabolic status, serum adiponectin, Hs-CRP & ICAM-1 (Intercellular Adhesion Molecule-1) levels in type 2 diabetic patients and regard to inclusion criteria : at least 6 months history of diabetes ; use of blood sugar lowering drugs; BMI $\leq$ 35, women 30-50 years and men age 30-60 and Exclusion Criteria: Pregnancy and lactation ; liver disease, kidney, heart disease, thyroid disease, inflammatory and ... ; Patients treated with insulin, lipid lowering drugs, diuretics, and use of dietary supplements, vitamins and minerals ; hormone therapy ; smoking ; change in dose of oral hypoglycemic drugs during the study ; taking antioxidant supplements at least three months before the study and during the study: at least 6 weeks prior to the intervention diet weight loss. Will be studied . 45 subjects were randomly divided into two groups (taking Fenugreek) and control (placebo) will be divided. Groups for 8 weeks, 10 grams of powdered Fenugreek and control 5 grams of starch in turn receive. Compounds every 2 weeks people will be delivered and to measure compliance with them at each visit, envelopes The case will be reviewed. complete inventory and assessment of general characteristics, anthropometric measurements (height and weight to calculate BMI) for each patient was performed to assess food intake questionnaire, reminder 24 hours for 3 days a week (2 days and 1 holiday) at baseline, end of week 4 and 8 of the study will be completed. individuals will be trained by the end of the study taking any supplements, not changing routine diet and exercise, report every changes . even if you do not wish to be notified and will have the right to withdraw from the study. From each of 10 ml blood sample after a 12-14 hour fast at the beginning and end of the intervention will be considered before taking

hypoglycemic agents. Measurement of fasting blood glucose levels, HbA1c, fasting serum insulin, insulin resistance, serum lipids, adiponectin, Hs-CRP and ICAM-1 in both groups before and after the intervention will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301263664N9**

Registration date: **2013-03-16, 1391/12/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-03-16, 1391/12/26

Registrant information

Name

Maryam Rafrat

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Nutritional Research Center of Tabriz University of Medical Sciences, Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-04-04, 1392/01/15
Expected recruitment end date
 2013-06-21, 1392/03/31
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Effects of fenugreek seeds consumption on metabolic status, serum adiponectin, Hs-CRP & ICAM-1 (Intercellular Adhesion Molecule-1) levels in type2 diabetic patients

Public title
 Effects of fenugreek seeds consumption on metabolic status, serum adiponectin, Hs-CRP & ICAM-1 (Intercellular Adhesion Molecule-1) levels in type2 diabetic patients

Purpose
 Supportive

Inclusion/Exclusion criteria
 Inclusion Criteria: Volunteered to Participate in The Study :At Least 6 Months History of Diabetes :Use of Blood Sugar Lowering Drugs: BMI $\leq$ 35, Women 30-50 Years and Men Age 30-60. Exclusion Criteria: Pregnancy and lactation :Liver Disease, Kidney, Heart Disease, Thyroid Disease, Inflammatory and ... :Patients treated with Insulin, Lipid Lowering Drugs, Diuretics, and Use of Dietary Supplements, Vitamins and Minerals :Hormone Therapy :Smoking: Change in Dose of Oral Hypoglycemic Drugs During The Study :Taking Antioxidant Supplements at Least Three Months before the Study and During The Study: at Least 6 Weeks Prior to The Intervention Diet Weight Loss

Age
 From **30 years** old to **60 years** old

Gender
 Both

Phase
 2-3

Groups that have been masked
No information

Sample size
 Target sample size: **90**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Research Ethics Committee of Tabriz University of Medical Sciences

Street address

Attar Neishaboori Avenue, Golgasht Atreet

City

Tabriz

Postal code

Approval date

2013-03-02, 1391/12/12

Ethics committee reference number

11673/4/5

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E11

ICD-10 code description

Non-Insulin-Dependent Diabetes Mellitus

Primary outcomes

1

Description

FBS

Timepoint

Before of Intervention and 8 Weeks After Intervention

Method of measurement

Blood Sampling and Analysing With Spectrophotometer

2

Description

HbA1C

Timepoint

Before of Intervention and 8 Weeks After Intervention

Method of measurement

Blood Sampling and Analysing With HPLC

3

Description

Level of Serum Insulin

Timepoint

Before of Intervention and 8 Weeks After Intervention

Method of measurement

Blood Sampling and Analysing With ELISA

4

Description

HOMA-IR

Timepoint

Before of Intervention and 8 Weeks After Intervention

Method of measurement

Calculated According to The Formula

5**Description**

Total Cholestrol

Timepoint

Before of Intervention and 8 Weeks After Intervention

Method of measurement

Blood Sampling and Analysing With Spectrophotometer

6**Description**

LDL-C

Timepoint

Before of Intervention and 8 Weeks After Intervention

Method of measurement

Calculated According to The Friedwald Formula

7**Description**

HDL-C

Timepoint

Before of Intervention and 8 Weeks After Intervention

Method of measurement

Blood Sampling and Analysing With Immunoturbidimetry

8**Description**

TG

Timepoint

Before of Intervention and 8 Weeks After Intervention

Method of measurement

Blood Sampling and Analysing With Spectrophotometer

9**Description**

Level of Serum Adiponectin

Timepoint

Before of Intervention and 8 Weeks After Intervention

Method of measurement

Blood Sampling and Analysing With ELISA

10**Description**

Level of Serum Hs-CRP

Timepoint

Before of Intervention and 8 Weeks After Intervention

Method of measurement

Blood Sampling and Analysing With Immunoturbidimetry

11**Description**

Level of Serum ICAM-1

Timepoint

Before of Intervention and 8 Weeks After Intervention

Method of measurement

Blood Sampling and Analysing With ELISA

Secondary outcomes

empty

Intervention groups**1****Description**

10 G of Powdered Fenugreek Seeds Twice a Day - 8 Weeks

Category

Treatment - Other

2**Description**

5 G Starch Twice a Day- 8 Weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Endocrinology clinic of Tabriz Sina Hospital

Full name of responsible person

Mina Malekiyan

Street address

Nutrition School, Attare Neishaboori Avenue, Golgasht Street

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Nutritional Reseach Center of Tabriz University of Medical Sciences

Full name of responsible person

Alireza Ostadrahimi

Street address

Nutrition School, Attare Neishaboori Avenue, Golgasht Street

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Nutritional Reseach Center of Tabriz University of

Medical Sciences
Proportion provided by this source
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

2

Sponsor

Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Mohamad Reza Rashidy
Street address
Tabriz University of Medical Sciences, Daneshgah Street
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, Tabriz University of Medical Sciences
Proportion provided by this source
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
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Fax
Email
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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