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 type2 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 type2 diabetic patients and regard to inclusion criteria :at least 6 months history of diabetes ؛ use of blood sugar lowering drugs؛BMI ≤ 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 Rafraf
Name of organization / entity
Tabriz University Of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Nutritional Reseach 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 Sudy ؛At Least 6 Months History of Dabetes ؛Use of Blood Sugar Lowering Drugs؛BMI ≤ 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 Detary 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

Diabet 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

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00
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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