Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

The effect of Fumaria Parviflora hydro-alcoholic extract on lipid profile, blood glucose indices, inflammatory factors, oxidative stress indices, and liver enzymes in patients with type 2 diabetes under a low-calorie diet

Protocol summary

Study aim

Determination of the effect of hydro-alcoholic fumaria Parviflora extract on lipid profile, blood glucose indices, inflammatory factors, oxidative stress indices, in patients with type 2 diabetes under a low-calorie diet

Design

The study will be performed as a double-blind randomized controlled clinical trial on 66 patients aged 2 to 6 years with type 2 diabetes. The RAS program is used for randomization.

Settings and conduct

This study will be performed on patients with type 2 diabetes in the age range of 20-65 years in the endocrinology department of Imam Reza Hospital in Tabriz.

Participants/Inclusion and exclusion criteria

inclusion criteria : 1.Patients who agree to participate 2.Women aged 20 to 50 years and men 20 to 65 years, 3.BMI range between 25 and 40 kg /m2, 4.Using blood-sugar-lowering drugs. Exclusion criteria : 1. Reluctance to participate in the study, 2.Insulin injection, 3.Use any nutritional supplements such as omega-3.Supplements or supplements that have anti-inflammatory and antioxidant properties in the past 3 months or during the study, 4. Liver and kidney failure and thyroid disease, 5. Smoking and alcohol consumption, 6. Patients using NSAIDs, corticosteroids, thiazide, and second-generation antipsychotics, 7. Pregnancy and desire to conceive during the study, 8. Intestinal and gastrointestinal diseases and eating disorders

Intervention groups

The intervention group will receive 550 mg hydroalcoholic extract of Fumaria parviflora once a day and one hour after breakfast, and the other group will receive 550 mg placebo capsules (cornstarch) one hour after breakfast.

Main outcome variables

Evaluation of the effect of hydro-alcoholic extract of fumaria Parviflora on lipid profile, blood glucose indices, inflammatory factors, oxidative stress indices, in patients with type 2 diabetes mellitus of a low-calorie diet,(BCL-2،Nrf-2،BAX، Nf-kB،MCP-1) gene expression

General information

Reason for update

Adding new factors (gene expression)

Acronym

IRCT registration information

IRCT registration number: **IRCT20130610013612N11**
Registration date: **2021-09-23, 1400/07/01**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-01, 1402/10/11**
Update count: **1**

Registration date

2021-09-23, 1400/07/01

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date
2021-11-21, 1400/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Fumaria Parviflora hydro-alcoholic extract on lipid profile, blood glucose indices, inflammatory factors, oxidative stress indices, and liver enzymes in patients with type 2 diabetes under a low-calorie diet

Public title
Effects of Fumaria Parviflora on diabetic patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who agree to participate in the study Women aged 20 to 50 years (non-menopausal) and men 20 to 65 years BMI range between 25 and 40 kg /m2 ; Having type 2 diabetes for at least 6 months while taking blood sugar-lowering drugs (metformin and thiazolidine)
Exclusion criteria:
Reluctance to participate in the study Insulin injection Use any nutritional supplements such as omega-3 supplements or supplements that have anti-inflammatory and antioxidant properties in the past 3 months or during the study Liver and kidney failure and thyroid diseases Smoking and alcohol consumption Patients using NSAIDs, corticosteroids (prednisone, prednisolone, and hydrocortisone), thiazide (furosemide and hydrochlorothiazide), and second-generation antipsychotics (olanzapine and clozapine). Pregnancy and desire to conceive during the study Intestinal and gastrointestinal diseases and eating disorders
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
In the current study, we will apply block randomization, one type of restricted randomization. Blocking is usually used to make a balance in the number of assigned samples to each studies group. This characteristic helps researchers in assigning an equal number of samples to each group, in cases that middle analyses are needed during the sampling process. The size of all the blocks is equal and in this two-group experiment, we will have 6 blocks (including 3 participants in the intervention group and 3 participants in the control group). Randomization tool also uses random allocation software that these random sequence generation software in addition to simple randomization are able to generate a random sequence by blocking method. For concealment, we use concealment allocation, which is the method used to execute a random sequence on study participants, so that the assigned group is not known before the individual is assigned. Using sealed opaque envelopes with random sequences (envelopes opaque, sealed, numbered sequentially) in which in this method each of the random sequences created is recorded on a card, and the cards inside the envelopes are placed in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed in a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes is opened in order and the assigned group of the participant is revealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
To reduce the bias or bias related to the intervention and the evaluation of outcomes, the double-blind method is used. In this way, the outcome can be measured objectively. In this method, the trial is planned in such a way that the participant and the researcher do not realize which of the two control or test groups they belong to.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Daneshgah Sq.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Approval date
2021-07-26, 1400/05/04
Ethics committee reference number
IR.TBZMED.REC.1400.378

Health conditions studied

1

Description of health condition studied
Type 2 diabetic patients
ICD-10 code
E08
ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Total cholesterol
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Blood Test

2

Description
Triglyceride
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Blood Test

3

Description
high-density lipoprotein
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Blood Test

4

Description
low-density lipoprotein
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Blood Test

5

Description
atherogenic index of plasma
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Blood Test

6

Description
Tumour Necrosis Factor alpha
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Blood Test

7

Description
interleukin 6
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Blood Test

8

Description
Intercellular Adhesion Molecule 1
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Blood Test

9

Description
Total antioxidant capacity
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Blood tests

10

Description
Malondialdehyde
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Blood tests

11

Description
glutathione peroxidase
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Blood tests

12

Description
Superoxide dismutase
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Blood tests

13

Description
Catalase
Timepoint
Baseline and 2 months after the intervention

Method of measurement
Blood tests

14

Description
MCP-1gene expression
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Measurement of gene expression by RT-PCR method

15

Description
Nf-kB gene expression
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Measurement of gene expression by RT-PCR method

16

Description
BAX gene expression
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Measurement of gene expression by RT-PCR method

17

Description
Nrf-2 gene expression
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Measurement of gene expression by RT-PCR method

18

Description
BCL-2 gene expression
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Measurement of gene expression by RT-PCR method

Secondary outcomes

1

Description
Anthropometric indecs
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Body composition measuring device

2

Description
Antropometric indices (Weight, Height, BMI, Waist circumference, Hip circumference, Waist to Hip Ratio)
Timepoint
Baseline and 2 months after the intervention
Method of measurement
Physical exam

Intervention groups

1

Description
Intervention group: receives 550 mg daily of hydro-alcoholic extract of fumaria Parviflora for 2 months
Category
Treatment - Other

2

Description
Control group: receive 550 mg daily of placebo consisting of cornstarch for 2 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Imam Reza Hospital
Full name of responsible person
Dr. Farzad Najafipour
Street address
Department of Endocrinology, Imam Reza Hospital, Tabriz University of Medical Sciences, Golgasht Street, Tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Samiei
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Vice chancellor for Research,Tabriz University of Medical Sciences, Golgasht Street, Tabriz
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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

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Farzad Najafipour
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable