Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Immunomodulatory effect of an herbal supplement containing Fenugreek, Nigella sativa and Sumac in patients with type 2 diabetes

Protocol summary

Study aim
Immunomodulatory effect of an herbal supplement containing Fenugreek, Nigella sativa and Sumac in patients with type 2 diabetes

Design
Double-blind clinical trial, 72 patients, 2 parallel groups by simple randomization.The trial phase is 3.

Settings and conduct
Patients visiting a center of traditional medicine clinic in Arak are divided into 2 groups by simple randomization with envelopes.The study is double-blind. Outcome elevator and analyzer and participant are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: fasting blood sugar is equal to or higher than 126 milligram per millilitre; taking oral hypoglycemic drugs; consumption of a fixed dose of oral hypoglycemic drugs for at least the last 3 months; lack of kidney failure; lack of type 1 diabetes; lack of acute and chronic inflammatory diseases; lack of malignancy; lack of drug addiction; no pregnancy or lactation. Exclusion criteria: dissatisfaction.

Intervention groups
Intervention group: In addition to the usual treatments for diabetes we treat patients with 6 capsules containing 3 Nigella sativa daily at a dose of 170 milligram, Fenugreek with a dose of 170 milligram, and Sumac with a dose of 170 milligram. Control group: In addition to conventional diabetes treatments, the placebo group will receive 6 capsules containing wheat flour containing 500 milligram for 6 weeks under the supervision of a traditional medicine specialist.

Main outcome variables
cytokine TGF-β; cytokine TNFα; cytokine IFN-γ; Cytokine IL-17; Number of Treg cells; Nitric oxide measurement

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N144**
Registration date: **2020-06-27, 1399/04/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-27, 1399/04/07**
Update count: **0**

Registration date
2020-06-27, 1399/04/07

Registrant information

Name
Fariba Farokhi

Name of organization / entity
Arak University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 86 3222 2003

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-05, 1399/02/16

Expected recruitment end date
2021-05-06, 1400/02/16

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Immunomodulatory effect of an herbal supplement containing Fenugreek, Nigella sativa and Sumac in patients with type 2 diabetes

Public title
Immunomodulatory effect of an herbal supplement containing Fenugreek, Nigella sativa and Sumac in patients with type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Fasting blood sugar is equal to or higher than 126 milligram per millileter Taking oral hypoglycemic drugs Consumption of a fixed dose of oral hypoglycemic drugs for at least the last 3 months Lack of kidney failure Lack of type 1 diabetes Lack of acute and chronic inflammatory diseases Lack of malignancy Lack of drug addiction No pregnancy or lactation
Exclusion criteria:
Dissatisfaction
Age
From **25 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple individual randomization with randomization with envelopes in 4 groups A and B . In this method, we write a few cards or letters as intervention groups and the same number of cards for the control group, then the cards are mixed. One card is taken out and its allocation is registered and the card is returned to the other cards after leaving. Then the cards are mixed again and then another card is picked up. This process continues to reach a random sequence according to sample size.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double blind. Outcome elevator and analyzer and participant are blind. Outcome elevator and analyzer and participant don't aware from grouping.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics comittee of Arak University of Medical Sciences
Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2020-05-03, 1399/02/14
Ethics committee reference number
IR.ARAKMU.REC.1399.043

Health conditions studied

1

Description of health condition studied
Type II diabetes
ICD-10 code
E08
ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Cytokine TGF-β
Timepoint
Before intervention and 6 weeks after the treatment
Method of measurement
Blood test

2

Description
Cytokine TNFα
Timepoint
Before intervention and 6 weeks after the treatment
Method of measurement
Blood test

3

Description
Cytokine IFN-γ
Timepoint
Before intervention and 6 weeks after the treatment
Method of measurement
Blood test

4

Description
Cytokine IL-17

Timepoint
Before intervention and 6 weeks after the treatment
Method of measurement
Blood test

5

Description
Number of Treg cells
Timepoint
Before intervention and 6 weeks after the treatment
Method of measurement
Blood test

6

Description
Nitric oxide measurement
Timepoint
Before intervention and 6 weeks after the treatment
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to the usual treatments for diabetes we treat patients with 6 capsules containing 3 Nigella sativa daily at a dose of 170 milligram, Fenugreek with a dose of 170 milligram, and Sumac with a dose of 170 milligram.
Category
Treatment - Drugs

2

Description
Control group: In addition to conventional diabetes treatments, the placebo group will receive 6 capsules containing wheat flour containing 500 milligram for 6 weeks under the supervision of a traditional medicine specialist.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Traditional Medicine Clinic
Full name of responsible person
Dr Mehdi Salehi
Street address
Emam reza clinic, Shahid Shirodi street
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3848176941
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+98 86 3222 2003
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Alireza Kamali
Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
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alikamaliir@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Dr Mehdi Salehi
Position
Assistant professor

Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
When we publish article in journal
When the data will become available and for how long
After the article is published
To whom data/document is available
Researcher in university
Under which criteria data/document could be used
If there are additional questions
From where data/document is obtainable
Dr Ali Ghazavi
What processes are involved for a request to access data/document
They have to write letters to the professors and the university.
Comments