

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of an herbal supplement containing Cinnamon, Cumin and Phyllanthus emblica on inflammatory response in type II diabetes

Protocol summary

Study aim

Effect of an herbal supplement containing Cinnamon, Cumin and Phyllanthus emblica on inflammatory response in type II diabetes

Design

Double-blind clinical trial, 50 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 evaluator 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, Eating bread in the diet and not getting celiac disease, 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 cinnamon plants daily at a dose of 170 milligram, cumin with a dose of 170 milligram, and Phyllanthus emblica 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 TNF α , 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: **IRCT20141209020258N142**
Registration date: **2020-06-16, 1399/03/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-16, 1399/03/27**

Update count: **0**

Registration date

2020-06-16, 1399/03/27

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of an herbal supplement containing Cinnamon, Cumin and Phyllanthus emblica on inflammatory

response in type II diabetes

Public title

Effect of an herbal supplement containing Cinnamon, Cumin and Phyllanthus emblica on inflammatory response in type II 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 Eating bread in the diet and not getting celiac disease 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

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

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 evaluator and analyzer and participant are blind. Outcome evaluator 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 committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square ,Sardasht,Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2020-05-10, 1399/02/21

Ethics committee reference number

IR.ARAKMU.REC.1399.058

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 TNF α

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 cinnamon plants daily at a dose of 170 milligram, cumin with a dose of 170 milligram, and Phyllanthus emblica 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

Treatment - Drugs

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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Phone

+98 86 3222 2003

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m.salehi@arakmu.ac.ir

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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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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Emam reza clinic, Shahid Shirodi street

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Maryam Khalatbari

Position

medicine student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr Ali Ghazavi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Person responsible for updating data**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person**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