

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Oct 2026

The effect of combination of *Eryngium Billardieri* and *Boswellia serrata* extracts on blood glucose, insulin, fasting insulin resistance index, lipid profile, and liver enzymes in type II diabetes patients

Protocol summary

Study aim

The effect of combination of *Eryngium Billardieri* and *Boswellia serrata* extracts on blood glucose, insulin, fasting insulin resistance index, lipid profile, and liver enzymes in type 2 diabetes patients

Design

The clinical trial has a control group, with parallel groups, double-blind, randomized, phase 2 on 60 type 2 diabetic patients. Excel software rand function was used for randomization.

Settings and conduct

We select 60 patients with type 2 diabetes referred to the Diabetes Center of Golestan Hospital in Ahvaz and randomly divide them into two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 50-35; only take oral medications; having fasting sugar above 140; willingness to participate in the study. Exclusion criteria: patients with liver cirrhosis; pregnant and lactating women; smoking and alcohol use; patients with retinopathy; people with active kidney disease; congestive heart failure and heart attack in the last six months; take insulin and other supplements.

Intervention groups

Intervention group 1(experimental group): using a drug made from the extract of *Eryngium Billardieri* and *Boswellia serrata*, which is about twenty-one milliliters (one-third is frankincense resin and two-thirds is borage) in addition to routine drugs. The second group (control group): placebo in addition to routine drugs.

Main outcome variables

Determination of fasting blood sugar and insulin levels, insulin resistance indices, insulin sensitivity, triglycerides, cholesterol, low-density lipoprotein, high-density lipoprotein, alkaline phosphatase, aspartate aminotransferase and alanine aminotransferase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111225008515N4**

Registration date: **2022-01-15, 1400/10/25**

Registration timing: **prospective**

Last update: **2022-01-15, 1400/10/25**

Update count: **0**

Registration date

2022-01-15, 1400/10/25

Registrant information

Name

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Name of organization / entity

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Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-19, 1400/10/29

Expected recruitment end date

2022-08-16, 1401/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combination of Eryngium Billardieri and Boswellia serrata extracts on blood glucose, insulin, fasting insulin resistance index, lipid profile, and liver enzymes in type II diabetes patients

Public title

"The effect of combination of Eryngium Billardieri and Boswellia serrata extracts on diabetes"

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Only take oral medications and do not take insulin and other supplements Having 250-140 fasting sugar Patients' willingness to participate in the study

Exclusion criteria:

Patients with liver cirrhosis Pregnant and lactating women Smoking and alcohol use Patients with active retinopathy and proliferative People with active kidney disease Congestive heart failure and heart attack in the last six months

Age

From **35 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization list is prepared by someone who is not in the study. The method of randomization will be based on the method of "randomization of balanced blocks", in which the number of people who will participate in the study, in order of entry into the study, are divided into blocks whose size is determined by the person. This number will remain hidden so that the people in the study are not aware of the size of the blocks. Assignment of each person in each block is done equally between the two groups by generating random numbers in Excel software. For example, if the block size is 4, in Excel software, 4 codes A and 2 codes B are written in 4 rows, and a random number is created in front of each of them, and by arranging these 4 rows based on random numbers, the codes are created. A and B will be randomly assigned to the members of this special block. This is done for other blocks as well. Assignment of codes A and B to the intervention and placebo will be done randomly by a third party and will be reopened after analyzing the data and summarizing

the results. The third party writes numbers from one to n (sample size) on the chewing gum packages based on a random allocation list, so that study participants and researchers will be unaware of the contents of the packages and groupings A and B. . The random allocation list will be opened after the data collection is completed to identify the two study groups for statistical analysis.

Blinding (investigator's opinion)

Double blinded

Blinding description

Code "A" and "B" will be assigned to each person in the study, and only the researcher will be aware of the type of groups. Clinical caregivers and participants are unaware of the groups. It should be noted that the extract is made and the placebo is similar in appearance, color and packaging.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committees of Ahvaz Jundishapur University of Medical Sciences

Street address

Esfand Ave, Golestan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2021-12-24, 1400/10/03

Ethics committee reference number

IR.AJUMS.REC.1400.595

Health conditions studied**1****Description of health condition studied**

type 2 diabets

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

fasting blood sugar above 140

Timepoint

Beginning and end of the study

Method of measurement

Using a glucometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In addition to routine medications, patients in this group are treated with extracts of Eryngium Billardieri and Boswellia serrata for 4 weeks. This combination is about twenty-one cc; One third of it is Boswellia serrata resin (about 7 cc) and two thirds of it is Eryngium Billardieri extract (about 14 cc) and is consumed after lunch.

Category

Treatment - Drugs

2

Description

Control group: This group, which is the control group, also receives placebo in addition to routine medications (for 4 weeks after lunch).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital Diabetes Center

Full name of responsible person

Mehrnoosh Zakerkish

Street address

Golestan Blv, Golestan hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

00S82

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Sorour Rajabalipour

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Akram Ahangarpour

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for updating data

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Only part of the data, such as glucose and lipid profile information, can be shared after identifying individuals.

When the data will become available and for how long

All this data is available in the article and everyone has access to it by preparing the complete file of the article.

To whom data/document is available

All this data is available in the article and everyone has access to it by preparing the complete file of the article.

Under which criteria data/document could be used

This data can be used by all people who study medicinal plants.

From where data/document is obtainable

To receive this data, you can correspond with the email of the project manager.

What processes are involved for a request to access data/document

To get the data, you can correspond with the executor of the project by email, and after checking the correspondence, the data will be provided to the person in an unrecognizable manner.

Comments