

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of consumption of hydro-alcoholic extract of *Eryngium Billardieri* with aerobic exercise on blood level and lipid profile in type 2 diabetic patients

Protocol summary

Study aim

The effect of *Eryngium Billardieri* herb consumption and aerobic exercise on blood glucose and lipid profile in type 2 diabetes patients

Design

A clinical trial with a control group, with two intervention groups, not blinded, randomized, phase 2 on 45 patients. The Rand function of Excel software will be used for randomization.

Settings and conduct

Subjects in the hydroalcoholic extract group will take two 100 mg capsules containing hydroalcoholic extract of *eryngium billardieri* plant in the morning and evening. Aerobic exercises will also be done 5 days a week, 60 minutes a day with moderate intensity. The study is not blinded and will take place in Qazvin city.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 35 to 60 years, Suffering from type 2 diabetes, Having fasting blood sugar between 150 and 200 mg/dL, Using metformin and sulfonyleurea drugs to control blood sugar, Following the diet given by a nutritionist; Exit criteria: Use of medicinal plants other than *Eryngium Billardieri* during the research

Intervention groups

The intervening variables of the research include the hydroalcoholic extract of the borage plant (as a capsule) and aerobic exercise. The application of the intervention variables in the groups is as follows: experimental group 1: the effect of *Eryngium Billardieri* plant + aerobic exercise, experimental group 2: the effect of aerobic exercise, and the control group: no use of *Eryngium Billardieri* and exercises. The duration of the intervention is six weeks.

Main outcome variables

Blood sugar variables and lipid profile will be taken and calculated on two occasions, before and after the end of

the study in the laboratory through blood sampling.

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20211116053081N2**

Registration date: **2022-10-16, 1401/07/24**

Registration timing: **prospective**

Last update: **2022-10-16, 1401/07/24**

Update count: **0**

Registration date

2022-10-16, 1401/07/24

Registrant information

Name

Zohreh Eskandari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 28 3369 1975

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2022-12-06, 1401/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of consumption of hydro-alcoholic extract of Eryngium Billardieri with aerobic exercise on blood level and lipid profile in type 2 diabetic patients

Public title
The effect of Eryngium Billardieri plant and aerobic exercise in diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age range 35 to 60 Suffering from type 2 diabetes
Having fasting blood sugar between 150 and 200 mg/dL
Using metformin and sulfonylurea group drugs (Glibenglamid, gliclazide, etc.) to control blood sugar
Following the diet given by the nutritionist Not using any medicinal plants other than Eryngium Billardieri during the research
Exclusion criteria:
Having regular physical activity (more than two sessions per week) during the last six months Inability to perform aerobic exercises due to physical diseases such as atherosclerosis, orthopedic problems, etc. Having diseases other than diabetes such as blood pressure, cardiovascular diseases and thyroid diseases

Age
From **35 years** old to **60 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Among the available patients (patients referred to Mohammadzadeh Clinic located in Qazvin city), 45 subjects will be selected and will be randomly assigned to two intervention groups and one control group through the rand function of Excel software. The method of using this software is as follows: in cells A2:A46, we enter all the names of 45 participants. Then we copy RAND formula in cells B2:B46: =RAND() Then we put the following formula in cell C2:C46 to extract a random value from column A:
=INDEX(SAS2:SAS46,RANK(B2,SBS2:SBS46),1) Fifteen initial names of cell C in the first experimental group, 15 middle names of cell C in the second experimental group, and 15 last names of cell C in the third group (in cell C, the names of cell A are placed randomly for For example, the person who is in cell A10 is now in cell C2).

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Ghazvin

City

Ghazvin

Province

Qazvin

Postal code

3419759811

Approval date

2022-07-06, 1401/04/15

Ethics committee reference number

<https://ethics.research.ac.ir/IR.QUMS.REC.1401.103>

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11.9

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Blood glucose

Timepoint

The beginning and the sixth week of study

Method of measurement

Serum blood (ELISA)

2

Description

Lipid profile

Timepoint

The beginning and the sixth week of study

Method of measurement

Autoanalyzer method

Secondary outcomes

empty

Intervention groups

1

Description

Receiving 100 mg capsules of eryngium billardieri twice a day in the morning and in the evening and aerobic exercises for six weeks, 5 days a week, 60 minutes every day with an average intensity of 50% to 75% of the maximum oxygen consumption.

Category

Treatment - Drugs

2

Description

Intervention group: aerobic exercises for six weeks, 5 days a week, 60 minutes every day with an average intensity of 50% to 75% of the maximum oxygen consumption.

Category

Treatment - Other

3

Description

Control group: Failure to receive eryngium billardieri and aerobic exercise, receiving blood sugar control drugs, metformin and sulfonylurea group drugs (Glybanglamid-Glyclazide, etc.)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammadzadeh Clinic

Full name of responsible person

Mohammad Reza Shiri Shahsavar

Street address

Mohammadzadeh Clinic, 12 Amirkabir Street, Nakhabgan Blvd., Jhanbazan Square, Qazvin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Raja University

Full name of responsible person

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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

Raja University

Proportion provided by this source

100

Public or private sector

Private

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

Qazvin University of Medical Sciences

Full name of responsible person

Mohammad Reza Shiri Shahsavar

Position

PhD in nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Food safety and Health

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Person responsible for scientific inquiries

Contact

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Other areas of specialty/work
Physiology
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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

I have no justification

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available