

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of six weeks of regular aerobic exercises with hydroalcoholic extract of *Eryngium billardieri* plant with aerobic exercises on fasting blood sugar and betatrophin serum levels in type 2 diabetic patients.

Protocol summary

Study aim

The effect of hydroalcoholic extract of *eryngium billardieri* plant along with aerobic exercise on fasting blood sugar and betatrophin serum levels in type 2 diabetic patients.

Design

45 eligible subjects will be randomly placed into two experimental groups and one control group through the rand function of Excel software: 1- a group of I extract of *eryngium billardieri* along with aerobic exercises 2- a group of aerobic exercises 3- control group (not receiving plant Bellows and aerobic exercise). The research design is unblinded, phase 1-2, factorial and therapeutic.

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

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 to control blood sugar. Following the diet given by the nutritionist, not using any medicinal plants other than *eryngium billardieri* during the research, ability to perform aerobic exercise.

Intervention groups

The present research includes three groups. In experimental group 1, the effect of hydroalcoholic extract of *eryngium billardieri* plant along with aerobic exercise and in experimental group 2, only the effect of aerobic exercise on dependent variables of blood sugar and betatrophin serum levels will be investigated. In the control group, *eryngium billardieri* and aerobic exercises will not be used.

Main outcome variables

After applying the intervention variables, blood sugar and betatrophin serum levels will be calculated as before the study through blood sampling in the laboratory.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211116053081N1**

Registration date: **2022-09-13, 1401/06/22**

Registration timing: **prospective**

Last update: **2022-09-13, 1401/06/22**

Update count: **0**

Registration date

2022-09-13, 1401/06/22

Registrant information

Name

Zohreh Eskandari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-11-06, 1401/08/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of six weeks of regular aerobic exercises with hydroalcoholic extract of Eryngium billardieri plant with aerobic exercises on fasting blood sugar and betatrophin serum levels in type 2 diabetic patients.

Public title
The effect of two therapeutic methods of regular aerobic exercise and Eryngium billardieri extract on type 2 diabetes patients

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
After selecting the eligible subjects, they will be randomly divided into three groups. To place each subject in one of the three groups, a lottery will be done in Excel in such a way that the names of all qualified people will be entered in a column in Excel, and finally, the RAND and RANDBETWEEN functions will be used to randomly select the subjects in the groups. will be used. Then the subjects will be placed in one of the following groups. 1- The group of taking hydroalcoholic extract of eryngium billardieri along with aerobic exercises. 2- The group of aerobic exercises. 3- The control group.

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

Ethics Committee of Ghazvin University of Medical Sciences

Street address

Shahid Bamonar Boulevard, Ghazvin

City

Ghazvin

Province

Qazvin

Postal code

5981134197

Approval date

2022-07-06, 1401/04/15

Ethics committee reference number

IR.QUMS.REC.1401.104

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 sugar

Timepoint

Beginning and end of the sixth week of study

Method of measurement

Serum blood (ELISA)

2

Description

Betatrophin serum levels

Timepoint

Beginning and end of the sixth week of stud

Method of measurement

By ELISA method using kit (ZEILBIO GmbH)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 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 2: 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 - Drugs

3

Description

Control group: Not using eryngium billardieri extract and aerobic exercises

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammadzadeh Clinic

Full name of responsible person

Mohammad Reza Shiri Shahsavari

Street address

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

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Mr.shiri@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Raja University

Full name of responsible person

Ali Yaghoubi

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Raja University, Norouzi st, Ghavin

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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 Shahsavari

Position

Assistant professor of nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Full name of responsible person

Zohreh Eskandari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Latest degree

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Other areas of specialty/work

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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