Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 l 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)

Phone

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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 Bahonar 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 (ZEllBIO 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 Shahsavar
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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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info@raja.ac.ir
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
Assistant professor of nutrition
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position

Assistant Professor

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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