

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Investigating the effect of a supplement of hydroalcoholic extract of Eryngium on the metabolic marker in type 2 diabetic patients

Protocol summary

Study aim

Determination of the effect of a supplement of hydroalcoholic extract of Eryngium on the metabolic marker in type 2 diabetic patients

Design

The clinical trial with two groups (intervention and control), pragmatic, double-blind, randomized

Settings and conduct

This study was conducted to evaluate the effect of hydroalcoholic extract of Eryngium on the metabolic marker in type 2 diabetic patients in the Diabetes Clinic of Sabzevar University of Medical Sciences. Clinical observant and participants will be unaware of how they are grouped. Patients will be randomized in the intervention group (hydroalcoholic extract of Eryngium) and in the control (placebo). The response to treatment is evaluated by metabolic markers at the end of the third month after the intervention for both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 2 diabetes for at least 2 years, HbA1C less than 8.5, Patients aged 20-60 years, Non-insulin treated diabetic patients. Exclusion criteria: Pregnancy and breastfeeding, Renal and cardiovascular disorders and chronic underlying disease, Insulin therapy, Micro and macro-vascular diabetic complications, Use of other herbal medicines that have an effect on diabetes, Smoking or alcohol abuse within a month before the study

Intervention groups

Intervention group: Patients in this group are treated with Hydroalcoholic extract of Eryngium (10 drops 3 times a day) for 3 months. (Each ml (28 drops) of this drug contains 924 mg of dry Eryngium). Control group: Patients in this group are treated with placebo (10 drops 3 times a day) for 3 months.

Main outcome variables

Determination of FBS, HbA1C, Triglyceride, cholesterol, LDL, HDL, creatinine, urea, alkaline phosphatase, aspartate aminotransferase, alanine aminotransferase

levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181006041252N7**

Registration date: **2019-01-25, 1397/11/05**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-25, 1397/11/05**

Update count: **0**

Registration date

2019-01-25, 1397/11/05

Registrant information

Name

Mohammad Sahebkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4401 8337

Email address

sahebkar@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of a supplement of hydroalcoholic extract of Eryngium on the metabolic marker in type 2 diabetic patients

Public title

Investigating the effect of a supplement of hydroalcoholic extract of Eryngium on the metabolic marker in type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetes for at least 2 years HbA1C less than 8.5
Patients aged 20-60 years Non-insulin treated diabetic patients

Exclusion criteria:

Pregnancy and breastfeeding Renal and cardiovascular disorders and chronic underlying disease Insulin therapy Micro and macro-vascular diabetic complications Use of other herbal medicines that have an effect on diabetes Smoking or alcohol abuse within a month before the study.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was conducted based on a permutation block, Accordingly, 42 blocks were allocated to patients, in each block, 2 were from following groups, treatment group A and group B. Eventually, after completing the blocks, Group A and B were treated with hydroalcoholic extract of Eryngium and Placebo tablet, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

Each person will be assigned a study code A and B, which will only be known to the researcher of the type of groups. The clinical observant and the participants are unaware of the groups. It should be noted that hydroalcoholic extract of Eryngium and placebo have been 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 committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar city

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Approval date

2019-01-19, 1397/10/29

Ethics committee reference number

IR.MEDSAB.REC.1397.099

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Determine Fasting Blood Sugar (FBS)

Timepoint

At the beginning of the study (before the intervention) and 3 months after starting the intervention

Method of measurement

Use of Auto-Analyzer machine and Spectrophotometric method

2

Description

Determination level of Glycosylated Hemoglobin (HbA1C)

Timepoint

At the beginning of the study (before the intervention) and 3 months after starting the intervention

Method of measurement

Use of Auto-Analyzer machine and Spectrophotometric method

3

Description

Determination level of Triglyceride

Timepoint

At the beginning of the study (before the intervention) and 3 months after starting the intervention

Method of measurement

Use of Auto-Analyzer machine and Spectrophotometric method

4

Description

Determination level of Cholesterol

Timepoint

At the beginning of the study (before the intervention) and 3 months after starting the intervention

Method of measurement

Use of Auto-Analyzer machine and Spectrophotometric method

5

Description

Determination level of Low-density Lipoprotein (LDL)

Timepoint

At the beginning of the study (before the intervention) and 3 months after starting the intervention

Method of measurement

Use of Auto-Analyzer machine and Spectrophotometric method

6

Description

Determination level of High-density Lipoprotein (HDL)

Timepoint

At the beginning of the study (before the intervention) and 3 months after starting the intervention

Method of measurement

Use of Auto-Analyzer machine and Spectrophotometric method

7

Description

Determination level of Creatinine

Timepoint

At the beginning of the study (before the intervention) and 3 months after starting the intervention

Method of measurement

Use of Auto-Analyzer machine and Spectrophotometric method

8

Description

Determination level of Urea

Timepoint

At the beginning of the study (before the intervention) and 3 months after starting the intervention

Method of measurement

Use of Auto-Analyzer machine and Spectrophotometric

method

9

Description

Determination level of Alkaline Phosphatase

Timepoint

At the beginning of the study (before the intervention) and 3 months after starting the intervention

Method of measurement

Use of Auto-Analyzer machine and Spectrophotometric method

10

Description

Determination level of Aspartate Aminotransferase (AST) (SGOT)

Timepoint

At the beginning of the study (before the intervention) and 3 months after starting the intervention

Method of measurement

Use of Auto-Analyzer machine and Spectrophotometric method

11

Description

Determination level of Alanine Aminotransferase (ALT) (SGPT)

Timepoint

At the beginning of the study (before the intervention) and 3 months after starting the intervention

Method of measurement

Use of Auto-Analyzer machine and Spectrophotometric method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group are treated with Hydroalcoholic extract of Eryngium (10 drops 3 times a day) for 3 months. (Each ml (28 drops) of this drug contains 924 mg of dry Eryngium)

Category

Treatment - Drugs

2

Description

Control group: Patients in this group are treated with placebo (10 drops 3 times a day) for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Sabzevar University of Medical Sciences

Full name of responsible person

Maede Salehabadi

Street address

Vasei Hospital, Tohid Blvd., Sabzevar Town

City

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Province

Razavi Khorasan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshte Ghorat

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshte Ghorat

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshte Ghorat

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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Maede Salehabadi

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Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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