

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The Effect of Fennel Supplements and Water Exercises on Esterogen Levels and some Metabolic Parameters in Diabetic Menopausal Women

Protocol summary

Study aim

The study of the effect of fennel supplements and exercise on estrogen and insulin levels and glucose and lipid profiles and physical signs of menopause in women with type 2 diabetes
پیشنهاد ویرایش درباره مترجم
حریم خصوصی و Google انجمن تلفن همراه درباره
شرایط راهنما

Design

The controlled clinical trials, community based and action-orientate parallel group, tree-blind, randomized,

Settings and conduct

Shahroud University of Technology

Participants/Inclusion and exclusion criteria

Female gender, history of type 2 diabetes, according to doctor's diagnosis, medical records, at least one year and no more than 5 years of menopause, no history of cardiovascular disease, and non-use of herbal remedies or complementary medicine, no use Sedation or anti-depressant drugs, no drug addiction or smoking, insulin use and no complications of diabetes, including diabetic foot ulcers, menopause, and post-menopausal hormone therapy

Intervention groups

Exercise and placebo group, Supplemental group, Supplement and exercise group, Placebo group.
Consumption: Soft FENNELIN capsule containing 100 mg of active ingredient in fennel and dumplings, the manufacture of Barij Essence, will be used in capsules of the same name labeled with R and H twice a day plus breakfast and dinner.

Main outcome variables

Insulin serum levels, Estrogen levels and level of serum glucose in postmenopausal women with type 2 diabetes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180709040404N1**

Registration date: **2019-01-08, 1397/10/18**

Registration timing: **prospective**

Last update: **2019-01-08, 1397/10/18**

Update count: **0**

Registration date

2019-01-08, 1397/10/18

Registrant information

Name

Shahrbanoo Rabiei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 23 3223 0457

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-15, 1397/10/25

Expected recruitment end date

2019-03-16, 1397/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Fennel Supplements and Water Exercises on Esterogen Levels and some Metabolic Parameters in Diabetic Menopausal Women

Public title

The impact of fennel and Aquatic supplement on menopausal symptoms and diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetes who are postmenopausal women with menopausal symptoms

Exclusion criteria:

Age

From **50 years** old to **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyster

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants and researchers and data analyst have been blinded to drugs and drugs

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahroud University of Medical Sciences

Street address

Shahrood University of Technology, University Boulevard, Shahrood

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Province

Semnan

Postal code

3619995161

Approval date

2018-05-23, 1397/03/02

Ethics committee reference number

IR.SHMU.REC.1397.380

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E10-E14

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

Estrogen levels in postmenopausal women with type 2 diabetes after 8 weeks of exercise in water and supplementation with fennel.

Timepoint

To measure the research variables, blood sampling is performed one day before the beginning of the training period, with 12 hours of fasting and 48 hours after the last session of the exercise.

Method of measurement

A blood sample of 5 centimeters of anti-cubital vein per person will be sitting in rest and resting. After 8 weeks of training in water, with fennel supplementation, the amount of estrogen, insulin and glucose will be measured. To determine estrogen levels, the radioimmune method (RIA) and the human estradiol kit will be used.

2

Description

Insulin serum levels in postmenopausal women with type 2 diabetes after 8 weeks of exercise in water and supplementation with fennel.

Timepoint

To measure the research variables, blood sampling is performed one day before the beginning of the training period, with 12 hours of fasting and 48 hours after the last session of the exercise.

Method of measurement

A blood sample of 5 centimeters of anti-cubital vein per person will be sitting in rest and resting. After 8 weeks of training in water, with fennel supplementation, the amount of estrogen, insulin and glucose will be measured. To measure insulin from methods A laboratory routine will be used

3

Description

The level of serum glucose in postmenopausal women with type 2 diabetes after 8 weeks of exercise in water and supplementation with fennel

Timepoint

To measure the research variables, blood sampling is performed one day before the beginning of the training period, with 12 hours of fasting and 48 hours after the

last session of the exercise.

Method of measurement

A blood sample of 5 centimeters of anti-cubital vein per person will be sitting in rest and resting. After 8 weeks of training in water, with fennel supplementation, the amount of estrogen, insulin and glucose will be measured. To measure glucose from methods A laboratory routine will be used

Secondary outcomes

1

Description

Lipid Profile (Includes Cholesterol, Triglyceride, HDL.LDL), Type 2 Methicillic-Type Postmenopausal Women. Study of Menopausal Symptoms of Type 2 Diabetic Women

Timepoint

To determine the level of lipid profile, blood transfusion is performed one day before the beginning of the exercise, with 12 hours of fasting and 48 hours after the last training session. Filling in the questionnaire for physical symptoms of menopause includes 11 questions (MRS) one day before the beginning of the exercise and 48 hours after the last training session

Method of measurement

In order to determine the lipid profile, blood sampling at 8:10 am to 5 centimeters of anticyclical vein from each patient will be performed in sitting position. A laboratory routine test will be used to measure serum lipid concentrations. For examination of the physical symptoms Menopause The MRS questionnaire will include 11 questions

Intervention groups

1

Description

First intervention group: water treatment group and fennel supplementation. Consumption: Soft FENNELIN capsule containing 100 mg effective ingredient in fennel and placebo, manufactured by «Barij Essence» , as capsules of the same name as R and H twice daily, plus breakfast and dinner. Will be consumed.

Category

Treatment - Other

2

Description

Second intervention group: Group exercise in water and placebo.

Category

Treatment - Other

3

Description

Third intervention group: Fennel supplement group. Consumption: Soft FENNELIN capsule containing 100 mg effective ingredient in fennel and placebo, manufactured

by «Barij Essence» , as capsules of the same name as R and H twice daily, plus breakfast and dinner. Will be consumed.

Category

Treatment - Other

4

Description

Control group: Group of placebo or comparison group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center of Azima Shahrud

Full name of responsible person

Dr Ehsan Binesh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrood University of Technology

Full name of responsible person

Dr Ali Hassani

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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

Shahrood University of Technology

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**

Shahrood University of Technology

Full name of responsible person

Dr. Ali Hassani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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student

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Effectiveness of fennel supplements and water exercises
on menopausal symptoms and diabetes mellitus in
diabetic menopause

When the data will become available and for how long

8 months after the intervention

To whom data/document is available

Researchers working in academic and academic institutions

Under which criteria data/document could be used

Academic research

From where data/document is obtainable

Sharbanoo Rabiei

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

Contact by email: sh.rabiei1357@gmail.com Review and answer up to a week

Comments

does not have