

# 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 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)

###### Phone

+98 23 3223 0457

###### Email address

Sh.rabiei@shahroodut.ac.ir

##### 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

##### **City**

shahrood

##### **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

##### **Street address**

Ferdowsi street

##### **City**

Shahrood

##### **Province**

Semnan

##### **Postal code**

3616713543

##### **Phone**

+98 23 3222 2065

##### **Fax**

+98 23 3222 2065

##### **Email**

sh.rabiei1357@gmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Shahrood University of Technology

##### **Full name of responsible person**

Dr Ali Hassani

##### **Street address**

7th Square

##### **City**

shahrood

##### **Province**

Semnan

##### **Postal code**

3616713432

##### **Phone**

+98 23 3445 5645

##### **Fax**

+98 23 3445 5646

##### **Email**

sh.rabiei@shahroodut.ac.ir

#### **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**

Physiology

**Street address**

7th Square

**City**

Shahrood

**Province**

Semnan

**Postal code**

3614513654

**Phone**

+98 232233208

**Fax****Email**

sh.rabiei@shahroodut.ac.ir

**Person responsible for scientific 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**

Exercise Physiology

**Street address**

7th Square

**City**

Shahrood

**Province**

Semnan

**Postal code**

3614773947

**Phone**

+98 23 3239 5054

**Email**

sh.rabiei@shahroodut.ac.ir

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

Shahrood University of Technology

**Full name of responsible person**

Shahrbanoo Rabiei

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiology of Exercise

**Street address**

Shahrood University of Technology, Shahrood blvd,  
Shahrood.

**City**

Shahrood

**Province**

Semnan

**Postal code**

3619995161

**Phone**

+98 23 3239 2204

**Fax**

+98 23 3239 2209

**Email**

sh.rabiei@shahroodut.ac.ir

**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