

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The assessment of Fenugreek extract's effect on early menopausal complications in symptomatic menopause women who refer to the clinic

#### Protocol summary

##### Summary

Women who refer to the clinic with the complaint of early menopause symptoms will be examined after giving consent to participating in research, and if they have inclusion criteria but not any exclusion criteria. In this study, we will use the convenient sampling and then the participants will be classified into 3 groups in the basis of random numbers. These groups are Fenugreek group, hormone therapy and placebo group. In Fenugreek extract group, two capsules each containing 500 mg extract of Fenugreek, equivalent to 6 grams of Fenugreek seeds, will be used daily (1 g total per day), after consultation with the pharmacologist and similar to analogous studies. In Hormone therapy group, two capsules containing 0/625 mg of conjugated estrogen and 2/5 mg of medroxy progesterone acetate powder will be used daily, and in the placebo group, two capsules containing lactose will be consumed daily. The duration of treatment will be 2 months. In this study, in order to evaluate the effect of the drug, climacteric Green questionnaire (Green's critical scale) will be used. In summary, before starting the study, every subject will complete two questionnaires: background variables questionnaire and Green questionnaire, and then in the fourth week and also in the eighth week after the intervention, Green questionnaire will be completed. finally, the groups' scores, after and before treatment, will be compared together.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138811283348N1**

Registration date: **2010-10-03, 1389/07/11**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2010-10-03, 1389/07/11

##### Registrant information

###### Name

Fatemeh Bakouei

###### Name of organization / entity

Midwifery group, Babol University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 1219 0597

###### Email address

bakouei@mubabol.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Babol University of Medical Sciences

##### Expected recruitment start date

2010-11-05, 1389/08/14

##### Expected recruitment end date

2011-05-20, 1390/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The assessment of Fenugreek extract's effect on early menopausal complications in symptomatic menopause women who refer to the clinic

##### Public title

Effect of Fenugreek extract (Trigonella foenum-graecum) on early menopausal complications

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion Criteria: -No any menstrual bleeding experience at least during last year. -Normal blood pressure. - In evaluation of Green questionnaire, the minimum score is 15. - FSH> 40. Exclusion Criteria: -The History of known disease or abnormality (e.g, breast cancer, uterine cancer, endometrial hyperplasia, angina, heart attacks, angioplasty, blood clot, kidney disease, liver disease, thyroid disease, diabetes, migraine headaches). - Abnormal vaginal bleeding - The use of special drugs or treatments like: hormonal therapy, nervous drugs, Corticosteroids drugs and anti-clot or herbal medicine during the past 6 months. - The use of relaxation techniques during the past 6 months. - Sensitivity to spices and essential oil materials -Smoking or drinking Alcohol.

## Age

From **45 years** old to **65 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **75**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Babol University of Medical Sciences

##### Street address

Ganj afroz street

##### City

Babol

##### Postal code

#### Approval date

2010-03-03, 1388/12/12

#### Ethics committee reference number

305728/ز.پ

## Health conditions studied

### 1

#### Description of health condition studied

early menopausal complications

#### ICD-10 code

N95.1

#### ICD-10 code description

Menopausal and female climacteric states

## Primary outcomes

### 1

#### Description

early menopausal complications

#### Timepoint

before intervention, fourth and eighth weeks after intervention

#### Method of measurement

Greene questionnaire

## Secondary outcomes

### 1

#### Description

side effects

#### Timepoint

fourth and eighth weeks after intervention

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

Fenugreek group: two capsules each containing 500 mg Fenugreek extract, daily

#### Category

Treatment - Drugs

### 2

#### Description

Hormone therapy group: two capsuls containing estrogen conjugate 0.625mg and medroxy progesteron acetat 2.5mg, daily

#### Category

Treatment - Drugs

### 3

#### Description

Placebo group: two capsules containing lactose, daily

#### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Ayatollah rohani Hospital Clinic

**Full name of responsible person**

Dr Basirat

**Street address**

Ganj afroz street

**City**

Babol

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr Ali Bijani

**Street address**

Ganj afroz street

**City**

Babol

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Babol University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

### Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Fatemeh Bakouei

**Position**

PHD student in reproductive health

**Other areas of specialty/work**

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### Person responsible for scientific inquiries

#### Contact

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Associate Professor

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### Person responsible for updating data

#### Contact

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**Other areas of specialty/work**

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**Postal code**

**Phone**

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**Fax**

**Email**

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**Web page address**

### Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*  
**Analytic Code**  
*empty*

**Data Dictionary**  
*empty*