

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

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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

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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