Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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 foenun-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/ژاپ

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 progestron 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
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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
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
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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