

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

the effect of chamomilla on early menopausal complications in menopausal women: (A double blind randomized controlled trial)

Protocol summary

Summary

This double blind randomized clinical trial includes 100 post menopausal syndrome patients who are referred to reproductive health research center. The Score Card Scale is used to assess the frequency and severity of menopausal symptoms. With regards to menopausal symptoms, the women are asked if they had experienced 20 symptoms in the last two weeks and grade its severity as mild, moderate or severe. Pelvic ultrasound or normal Pelvic exam and blood sample for serum FSH was taken at baseline of the treatment or two years of Imp. The informed consent is obtained from patients. Patients are divided randomly in two treatment groups. One group receive chamomile capsule (400 mg with apajenie 1.2% for QID) and the other one receive placebo capsule for 12 weeks. The Score Card Scale is evaluated after 4, 8, 12 weeks treatment again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902203902N1**

Registration date: **2011-03-06, 1389/12/15**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-03-06, 1389/12/15

Registrant information

Name

Farideh Mohsenzadeh

Name of organization / entity

Babol university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2012-12-20, 1391/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of chamomilla on early menopausal complications in menopausal women: (A double blind randomized controlled trial)

Public title

Assessment the effect of chamomilla on early menopausal complications in menopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: A total score of more than 15 (means that the women needs a hormone replacement therapy), normal pelvic ultrasound or normal pelvic exam , and FSH>40 or two years of Imp. Exclusion criteria: Women who received hormone therapy during the last 6 months, on a diet or herbal treatment; hypercholesterolemia, thyroid disorders, hypertension, diabetes, family history of heart disease, cigarette smoking, serious illnesses (malignancy)

Age

From **47 years** old to **62 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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 sceinces

Street address

Babol university of medical sceinces

City

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Postal code

4713838149

Approval date

2010-06-25, 1389/04/04

Ethics committee reference number

30804

Health conditions studied

1

Description of health condition studied

menopause complication

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Reduce of menopause complications

Timepoint

4 & 8 &12 weeks later

Method of measurement

Scorecard Scale

Secondary outcomes

1

Description

Enjoyed life

Timepoint

4&8&12weeks later

Method of measurement

Scorecard Scale

Intervention groups

1

Description

Intervention group: 4 100mg-caps of chamomilla, daily for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: 4 caps of placebo, daily for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol university of medical sciences

Full name of responsible person

Farideh mohsenzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol university of medical sciences

Full name of responsible person

Amrollah Mostafazadeh

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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****Name of organization / entity**

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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