

# 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)

##### Phone

+98 11 1229 8582

##### Email address

f.mohsenzadeh@mubabol.ac.ir

##### 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**

Babol

**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

**Street address**

Babol university of medical sciences

**City**

Babol

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Babol university of medical sciences

**Full name of responsible person**

Amrollah Mostafazadeh

**Street address**

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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**

Babol university of medical sciences

**Full name of responsible person**

Shahla Yazdani

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Obstetric & Gynecologist/faculty member

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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*