

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the effectiveness of basil capsules on the quality of life of postmenopausal women

Protocol summary

Study aim

Determining the effectiveness of basilicum L Ocimum capsule on the quality of life of postmenopausal women

Design

Clinical trial with intervention and control groups with parallel, double-blind, randomized groups was performed on 88 patients. Blocked randomization was performed using software.

Settings and conduct

The setting was Alborz University clinics. This study was double-blind (the researcher and the patients).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Postmenopausal women, married, 45-65 years. Exclusion criteria: the history of cancer and/or chemotherapy, premature menopause; consumption of psychiatric drugs; allergies to the group of Lamiaceae plants

Intervention groups

In the intervention group, eligible postmenopausal women took 250 mg basilicum L Ocimum capsules twice a day for 4 weeks. In the control group, placebo capsules were given in the same way. The shape, size, weight, and color of the placebo were exactly the same as the main capsule.

Main outcome variables

Quality of life of postmenopausal women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180110038302N7**

Registration date: **2021-08-28, 1400/06/06**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-28, 1400/06/06**

Update count: **0**

Registration date

2021-08-28, 1400/06/06

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of basil capsules on the quality of life of postmenopausal women

Public title

The effect of basil capsule on the quality of life of postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Postmenopausal women Married 45-65 years

Exclusion criteria:
premature menopause History of malignancies or chemotherapy History of mental illness or history of taking neuroleptics Sensitive to the group of mint plants

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Balance Randomization (quadruple) was accomplished with software. In this method size of all blocks was equal. In this study with a sample size of 88, the number of blocks was 22 and the size of each block was 4. The number of participants in the control and intervention groups was equal (44 in each group).

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind the participants, the capsules were completely similar and there was no difference between the capsules of the placebo and the capsules containing the basil plant.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Alborz University of Medical Science

Street address

No. 79, Unit 1, Kosar Complex, Sepehr St., Darakhti St., Dadman Blvd., Gharb Town

City

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Province

Tehran

Postal code

1468695393

Approval date

2021-02-08, 1399/11/20

Ethics committee reference number

IR.ABZUMS.REC.1400.026

Health conditions studied

1

Description of health condition studied

Menopausal symptoms and quality of life

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Quality of life of postmenopausal women

Timepoint

Before intervention and 28 and 60 days after starting consumption

Method of measurement

Postmenopausal women quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients receive 250 mg capsules of basil containing sifted plant powder for one month and twice a day. The capsules are made by the researcher himself.

Category

Treatment - Drugs

2

Description

Control group: people take placebo. Placebo capsules are similar to the original medicine capsule and should be taken in the same number.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics affiliated to Alborz University of Medical Sciences

Full name of responsible person

Mansoorh Yazdkhusti

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Sponsors / Funding sources

1

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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
Alborz medical science university
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to

make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to
make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to
make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable