Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 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
Mansoureh Yazdkhasti

Name of organization / entity
Alborz University medical science

Country
Iran (Islamic Republic of)

Phone
+98 21 4401 8856

Email address
m.yazdkhasti@abzums.ac.ir

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
Tehran

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
Mansooreh Yazdkhusti

Street address
West Buali street, Alborz University of Medical

Sciences
City
Karaj
Province
Alborz
Postal code
3149969415
Phone
+98 26 3428 7483
Email
Mansoyazd@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz medical science university
Full name of responsible person
Mansooreh Yazdkhusti
Street address
West Buali street, Alborz University of Medical
City
Karaj
Province
Alborz
Postal code
3149969415
Phone
+98 26 3264 2815
Email
Mansoyazd@yahoo.com
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

Contact
Name of organization / entity
Alborz medical science university
Full name of responsible person
Mansooreh Yazdkhusti
Position
Associate professo
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
West Buali street, Alborz University of Medical Sciences
City
Karaj
Province
Alborz
Postal code
3149969415
Phone
+98 26 3428 7483
Fax
Email
Mansoyazd@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Alborz University of Medical Sciences
Full name of responsible person
Mansooreh Yazdkhusti
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
West Buali street, Alborz University of Medical Sciences
City
karaj
Province
Alborz
Postal code
3149969415
Phone
+98 26 3428 7483
Email
Mansoyazd@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Alborz University of Medical Sciences
Full name of responsible person
Fateme Zokaei
Position
Midwife
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
West Buali street, Alborz University of Medical Sciences

City
Karaj
Province
Alborz
Postal code
3149969415
Phone
+98 26 3428 7483
Email
sara_ghorbannejad25@yahoo.com

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