Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of a Menohelp Barij® capsule on early symptoms of menopause: a randomized placebo-controlled trial

Protocol summary

Study aim
To determine effect of Menohelp Barij® herbal capsule on early menopausal symptoms

Design
Randomized superiority placebo-controlled double blind trial with two parallel arms: 100 participants will be allocated into the groups using stratified block randomization.

Settings and conduct
Eligible menopausal women will be identified through the "SIB" computerized program from Tabriz health centers, invited to participate into the study through phone call, and recruited into the study after getting informed consent. The women will be randomly allocated into Menohelp Barij® or placebo groups. Sequentially numbered packages containing Menohelp Barij® or placebo will be used to conceal the allocation. The capsules, identical in appearance, will be identically packed, and given to participants in order of their inclusion into the study. Sequence generation and preparation of the packs will be done by a person not involved in the participant recruitment and data collection. The investigator involved in participant recruitment, data collectors and the participant will be blinded until end of study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: health women aged 50-59 years old, 12-72 months after the last menstrual period, natural menopause, having at least 3 hot flashes daily during one week follow-up, living with husband, BMI 18-30, at least 6 years education. Exclusion criteria: Contraindications for hormone therapy, hormone therapy during past 3 months, surgery in the past 3 months; history of any chronic diseases, history of fibromyoma; heavy smokers.

Intervention groups
Intervention group: receiving Menohelp Barij® capsule 550 mg; Control group: receiving placebo; both produced by Barij-Essence pharmaceutical company, Kashan-Iran; once daily for 90 days

Main outcome variables
Total score and sub-domains of early menopausal symptoms; number and severity of hot flashes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100414003706N35**
Registration date: **2020-01-03, 1398/10/13**
Registration timing: **prospective**

Last update: **2020-01-03, 1398/10/13**
Update count: **0**

Registration date
2020-01-03, 1398/10/13

Registrant information

Name
Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3477 2699

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alizades@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-21, 1398/11/01

Expected recruitment end date
2020-05-19, 1399/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of a Menohelp Barij® capsule on early symptoms of menopause: a randomized placebo-controlled trial

Public title
Effect of a Menohelp Barij® capsule on early symptoms of menopause
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Aged 50-59 years 12-72 months after last menstrual period Natural menopause Having at least 3 hot flashes daily during one week follow-up Living with husband BMI 18 to 30 kg/m2 Having a least 6 years Education
Exclusion criteria:
Contraindications for hormone therapy, including history of breast cancer, endometrial hyperplasia, or any estrogen-related cancers in the woman or her first-degree family Use of hormone therapy during past 3 months Allergy to estrogen or medicinal herbs Any history of cervical cancer, liver diseases, kidney diseases, gastrointestinal diseases, coagulation diseases, depression or hyperthyroidism. Surgery during the past 3 months Chronic diseases requiring treatment including severe hypertension (160/110) and known diabetes, or malabsorption syndrome Myocardial or cerebral infarction over the past 3 months or History of complicated myocardial or cerebral infarction History of venous thrombosis history of known fibromyoma Heavy smoker (more than 15 cigarettes/day) Regular consumption of alcoholic beverages and alcohol dependence
Age
From **50 years** old to **59 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible women will be individually allocated into intervention (Menohelp Barij®) or control (placebo) groups using stratified (based on menopause duration of less than 3 years/3 years or more) block randomization with block size of 4 and with allocation ratio of 1:1. Allocation sequence will be generated using a computer software. Sequentially numbered packages containing Menohelp Barij® or placebo will be used to conceal the allocation. Sequence generation and preparation of packages will be done by a person not involved in the participant recruitment and data collection.
Blinding (investigator's opinion)
Double blinded
Blinding description
The Menohelp Barij® and placebo capsules, identical in appearance, will be identically packed; two packs for each participant, the first pack containing 30 tablets for the first month intake and the second pack containing 60 tablets for the second and third months intake. Sequentially numbered packages will be used for the allocation concealment .The packs will be given to participants in order of their inclusion into the study. The investigator involved in participant recruitment, data collectors and the participant will be blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Ave., Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date
2019-12-10, 1398/09/19
Ethics committee reference number
IR.TBZMED.REC.1398.970

Health conditions studied

1

Description of health condition studied
The early menopausal symptoms
ICD-10 code
N95
ICD-10 code description
Menopausal and other perimenopausal disorders

Primary outcomes

1

Description
overall score and sub-scales (vasomotor, physical, psychological, and sexual symptoms) of early menopausal symptoms
Timepoint
Before intervention and 4 and 12 weeks after intervention
Method of measurement
Green climacteric scale

2

Description
Number of daily hot flashes
Timepoint
before intervention and 4 and 12 weeks after intervention
Method of measurement
daily registration form

3

Description
severity of hot flashes
Timepoint
before intervention and 4 and 12 weeks after intervention
Method of measurement
daily registration form

Secondary outcomes

1

Description
total and subscales scores of quality of life
Timepoint
before intervention and 12 weeks after intervention
Method of measurement
The Menopause-Specific Quality of Life (MENQOL)

2

Description
total improvement status for early symptoms of menopause
Timepoint
4 and 12 weeks after intervention
Method of measurement
one question with three Likert options

3

Description
Quality of sleep score
Timepoint
4 weeks after intervention
Method of measurement
The Pittsburgh Sleep Quality Index (PSQI)

Intervention groups

1

Description
Intervention group: Recieving Menohelp Barij® 550 mg Herbal Capsule , containing Extracts of Actaea racemosa L., Glycine max , Dioscorea villosa, Arctium lappa and Vitex agnus- castus; standardized based on at least 40 mg total phenolic according to daidzein and 3 mg diosgenin in each capsule, produced by Barij Essence Pharmaceutical company, Kashan-Iran; once daily for 90 days.
Category
Treatment - Drugs

2

Description
Control group: placebo capsules identical to Menohelp Barij® herbal capsules; produced by Barij Essence Pharmaceutical company, Kashan-Iran; once daily for 90 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Public Health Centers
Full name of responsible person
Dr Ali Ebadi
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Tabrizphc@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Barij Essence Pharmaceutical Company
Full name of responsible person
Laleh Hejazi
Street address
Mashhad Ardehal, P.O.Box: 1178
City

Kashan
Province
Isfehan
Postal code
3795191916
Phone
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Email
drbekhradi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Barij Essence Pharmaceutical Company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Barij Medicinal Plants Research Center
Full name of responsible person
Reza Bekhradi
Position
Researcher of Barij Medicinal Plants Research Center
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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alizades@tbzmed.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All deidentified IPD can be shared.

When the data will become available and for how long

Starting soon after publication of the study results for ten years.

To whom data/document is available

Data will be available for researchers working in academic institutions, as well as to chief editor and reviewers of the submitted manuscript.

Under which criteria data/document could be used

The data will be available to researchers upon request and submission of the proposal to perform meta-analysis using IPD. Also, in exceptional cases, data will be made available to chief-editor of the journals for checking.

From where data/document is obtainable

Refer to the email addresses (alizades@tbzmed.ac.ir, drbekhradi@barijessence.com).

What processes are involved for a request to access data/document

The requests should be sent by email and data will be available within two week.

Comments