Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of a Rheum officinale on Hot Flashes in Menopausal women compared with placebo.

Protocol summary

Study aim
The effectiveness of a Rheum officinale on hot flashes in menopausal women compared to placebo.

Design
Clinical trials with control group, with parallel groups, blind, randomized

Settings and conduct
The study is a double-blind clinical trial in Tehran's health care centers. Among 90 menopausal women with hot flashes based on the inclusion criteria, they were selected and received consent after entering the study,The personal and medical information questionnaire is completed for each patient and they are asked to complete and deliver a questionnaire on the severity of hot flash before treatment,The drug packets that are numbered randomly in a double blind form are given to the patients and randomly divided into two groups of rheum and placebo, then received a drug or placebo. The method of use is explained, women in the first group receive 500 mg of rheum twice a day for 8 weeks ,the second group of 500 mg of placebo twice a day for 8 weeks .After 8 weeks of treatment, the hot flashes questionnaire will be completed again by them

Participants/Inclusion and exclusion criteria
Inclusion criteria: En Women who have not experienced menstruation in last 12 months The complainant of hot flashes Lack of medical illness or medication during the study No addiction or smoking Have at least reading and writing literacy Possibility of patient tracking consent to enter the study Exclusion criteria: Use of chemical medicine to treat hot flashes Use a herbal medicine or a special diet to treat hot flashes The disease is known during the study There is a history of allergy to the drug or herbal compounds History of intestinal surgery

Intervention groups
Therapeutic intervention:500 mg of rheum twice a day for 8 weeks Placebo intervention: 500 mg of placebo twice a day for 8 weeks

Main outcome variables
decrease of the severity, frequency and duration of hot flashes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181015041345N1**
Registration date: **2019-05-06, 1398/02/16**
Registration timing: **prospective**

Last update: **2019-05-06, 1398/02/16**
Update count: **0**

Registration date
2019-05-06, 1398/02/16

Registrant information

Name
najmeh bagheriani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 5558 0388

Email address
bagheriani.n@tak.iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2019-09-23, 1398/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of a Rheum officinale on Hot Flashes in Menopausal women compared with placebo.

Public title
The effectiveness of a Rheum officinale on Hot Flashes.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women who have not experienced menstruation in last 12 months The complainant of hot flashes Lack of medical illness or medication during the study No addiction or smoking Have at least reading and writing literacy Possibility of patient tracking consent to enter the study

Exclusion criteria:
Use of chemical medicine to treat hot flashes Use a herbal medicine or a special diet to treat hot flashes The disease is known during the study There is a history of allergy to the drug or herbal compounds History of intestinal surgery

Age
From **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization is done by Randomizer software, before starting the trial. Patients who have inclusion criteria, are randomly assigned into one of the two groups: Drug or placebo capsul.

Blinding (investigator's opinion)
Double blinded

Blinding description
Absence of knowledge of the participants and the clinical care observant and principal researcher of the drug or placebo capsul

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical commitee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences,next to Milad Tower, Hemmat Highway

City
tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2019-02-24, 1397/12/05

Ethics committee reference number
IR.IUMS.REC.1397.1286

Health conditions studied

1

Description of health condition studied
flushing

ICD-10 code
R23.2

ICD-10 code description
Flushing

Primary outcomes

1

Description
flushing questionnaire score

Timepoint
immediately before initiation of intervention, one month and two months after intervention

Method of measurement
questionnaire score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 500 mg of rheum twice a day for 8 weeks

Category
Treatment - Drugs

2

Description

Control group: 500 mg of pharmaceutical starch twice a day for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers In Tehran Province

Full name of responsible person

Najmeh Bagheriani

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No.847, Beginning of behesht Street, South Park City, Vahdat Islamic Street, Hassan Abad Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Iran University of Medical Sciences

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

Iran University of Medical Sciences

Full name of responsible person

Najmeh Bagheriani

Position

MD, PhD Candidate

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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

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

Clinical Study Report
Undecided - It is not yet known if there will be 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