

# 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 committee 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

۱۴۲۹۶۱۴۵۳۵

#### 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

**Street address**

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

**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

bagheriani.n@tak.iums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Najmeh Bagheriani

**Street address**

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

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admins@iums.ac.ir

**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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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

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## Person responsible for updating data

### Contact

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Iran University of Medical Sciences

**Full name of responsible person**

Najmeh Bagheriani

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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