Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of Urtica dioica with placebo in hot flashes during menopause.

Protocol summary

Study aim
Comparison of the Effect of Urticaria dioica with Placebo in hot flash of Postmenopausal Women.

Design
Randomized, double blinded, placebo controlled, community based pragmatic clinical trial with a parallel group

Settings and conduct
Chinese and Complementary Medicine clinic & Gynecology clinic, Imam Reza Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: Post-menopausal women (defined as: amenorrhea for 12 months or more) who suffer from hot flashes; Age 45-60 years old; Approval for treatment of hot flashes; Consent to participate in the study. Exclusion Criteria: History of hysterectomy or oophorectomy; Anticancer therapies due to malignancy; History of estrogen-dependent cancers over the past five years; History of allergy to urticaria; History of known psychiatric disorders; Hyperthyroidism or hypothyroidism; ;Cardiovascular disease (coronary artery disease, cerebrovascular disease and thromboembolic disorders); Uncontrolled Hypertension; Uncontrolled diabetes; Kidney or liver failure; Use of anticoagulants; Taking any medication for hot flashes such as HRT and SSRI in the past eight weeks; Endometrial thickness over 12 mm in uterine ultrasonography; Vaginal bleeding with unknown origin in the past 6 months

Intervention groups
Intervention group: Urticaria dioica in the form of Urtidin tablet 150 mg, 3 times/ day for 7 weeks. Control group: placebo tablets three times a day for 7 weeks.

Main outcome variables
Number and severity of hot flashes; measurement of LH and FSH and estradiol MRS questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110809007265N11**
Registration date: **2018-05-23, 1397/03/02**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-04, 1397/08/13**
Update count: **1**

Registration date
2018-05-23, 1397/03/02

Registrant information

Name
Hoda Azizi

Name of organization / entity
Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-18, 1397/02/28

Expected recruitment end date
2018-06-18, 1397/03/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Urtica dioica with placebo in hot flashes during menopause.

Public title
Effect of Nettle in treatment of menopausal hot flash
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Post-menopausal women (defined as: amenorrhea for 12 months or more) who suffer from hot flashes. Age 45-60 years old Approval for treatment of hot flashes and consent to participate in the plan.
Exclusion criteria:
History of hysterectomy or oophorectomy Anticancer therapies due to malignancy History of estrogen-dependent cancers over the past five years History of allergy to urticaria History of known psychiatric disorders Hyperthyroidism or hypothyroidism Conditions and physical illnesses that are not suitable for this study: Cardiovascular disease (coronary artery disease, cerebrovascular disease and thromboembolic disorders) uncontrolled Hypertension or diabetes, kidney or liver failure use of anticoagulants Taking any medication for hot flashes such as HRT and SSRI in the past eight weeks Endometrial thickness over 12 mm in uterine ultrasonography Vaginal bleeding with unknown origin in the past 6 months
Age
From **45 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Sealed envelopes
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, researcher, questioner, and data analyzer will be blind in this study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Mashhad University of Medical Sciences, Daneshgah Street
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Province
Razavi Khorasan
Postal code
91357345
Approval date
2018-05-07, 1397/02/17
Ethics committee reference number
IR.MUMS.REC.1396.335

Health conditions studied

1

Description of health condition studied
Menopause
ICD-10 code
N95.1
ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
Level of FSH, estradiol, LH
Timepoint
Before the study and at week 8
Method of measurement
blood test

2

Description
Severity of menopausal symptoms
Timepoint
Before the intervention, week 4 and 7
Method of measurement
Menopausal Rating Scale questionnaire

3

Description
Number and severity of hot flashes per day
Timepoint
One week before the study and at weeks 5 and 8
Method of measurement
Patient Daily Report

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: nettle in the form of Urtidin tablet 150 mg, 3 times/ day for 7 weeks.
Category
Treatment - Other

2

Description
Control group: nettle placebo tablet, three times a day for seven weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Chinese and Complementary clinic of Imam Reza Hospital
Full name of responsible person
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2

Recruitment center
Name of recruitment center
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr Hoda Azizi
Position
Clinical Ph.D./Assistant professor
Latest degree
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Other areas of specialty/work
Acupuncturist
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Person responsible for updating data

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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