Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of Urtica dioica, acupuncture and their combined therapy on hot flashes during menopause

Protocol summary

Study aim
Comparison of effect of nettle, acupuncture and combined treatment with placebo in menopausal hot flashes

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
1-Intervention group 1: Nettle in the form of an orthodine tablet with a dose of 150 mg three times a day and an acupuncture twice a week for 7 weeks. 2- Intervention group 2: Placebo of Nettle three times a day and acupuncture twice a week for 7 weeks. 3- Intervention 3: Nettle in the form of an orthodine pill with a dose of 150 mg every three times a day and an acupuncture twice a week for 7 weeks. 4-Placebo group: Placebo of Nettle three times a day and tampon acupuncture twice a week 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: **IRCT201707017265N10**
Registration date: **2017-08-13, 1396/05/22**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-25, 1397/08/03**
Update count: **1**

Registration date
2017-08-13, 1396/05/22

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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+98 51 1855 2188

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Recruitment status
Recruitment complete

Funding source
Deputy of Research of Mashhad University of Medical Sciences

Expected recruitment start date
2017-08-11, 1396/05/20

Expected recruitment end date

2017-12-11, 1396/09/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Urtica dioica, acupuncture and their combined therapy on hot flashes during menopause

Public title
Treatment of menopause by Nettle and acupuncture

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:

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: **68**

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
Deputy of research, Mashhad University of Medical Sciences

Street address
Mashhad University of Medical Sciences, Daneshgah Street

City
Mashhad

Province
Razavi Khorasan

Postal code
91357345

Approval date
2017-07-15, 1396/04/24

Ethics committee reference number
IR.MUMS.REC.1396.144

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 5 and 8

Method of measurement
Menopausal Quality of Life 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
Acupuncture, two sessions/week from week 1 to 4, and one session/week through weeks 5 to 7 + nettle in the form of Urtidin tablet 150 mg, 3 times/ day for 7 weeks.
Category
Treatment - Other

2

Description
Acupuncture, two sessions from week one to fourth and one session at week five through seventh + placebo nettle, once every three weeks for seven weeks.
Category
Other

3

Description
Acupuncture sham, two sessions from week one to fourth, and one session in the fifth to seventh week + nettle in the form of a 150 mg orthidine tablet every three times for seven weeks.
Category
Other

4

Description
Acupuncture sham, two sessions from week one to fourth and one session at week five to seven + placebo nettle three times a day for seven weeks
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Acupuncture clinic of Imam Reza Hospital
Full name of responsible person
Dr. Hoda Azizi
Street address
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2

Recruitment center
Name of recruitment center
Gynecology Clinic of Imam Reza Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
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Deputy of research office, MUMS central office, Daneshgah street
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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
Vice chancellor for research, 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
Ph.D.

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