

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 1855 2188

###### Email address

azizih@mums.ac.ir

##### 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

**City**

Mashhad

**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

Dr. Hoda Azizi

##### Street address

Daneshgah Street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913316

##### Phone

+98 51 3802 2035

##### Email

azizih@mums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Gynecology Clinic of Imam Reza Hospital

##### Full name of responsible person

Dr. Seyyedeh Azam Pourhoseini

##### Street address

Imam Reza Square, Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913316

##### Phone

+98 51 3854 3031

##### Email

Pourhoseinia@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr. Mohsen Tafaghodi

##### Street address

Deputy of research office, MUMS central office, Daneshgah street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91357345

##### Phone

+98 51 3459 1357

##### Email

tafaghodim@mums.ac.ir

#### 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

Ph.D.

##### Other areas of specialty/work

Acupuncturist

##### Street address

Department of Chinese and complementary medicine, School of traditional and complementary medicine, University Campus, Azadi Square

##### City

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 3882 9279

**Email**

azizih@mums.ac.ir

**Person responsible for scientific 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**

Acupuncture

**Street address**

Department of Chinese and complementary medicine,  
School of traditional and complementary medicine,  
University Campus, Azadi Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 3882 9279

**Email**

azizih@mums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Raheleh Kargozar

**Position**

PhD student of Traditional Medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Iranian Medicine

**Street address**

School of Iranian and Complementary Medicine,  
University campus, Azadi Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 3882 9279

**Email**

kargozarr931@mums.ac.ir

**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