

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The comparison of the effect of acupuncture and drug therapy on controlling hot flash and sleep disorders in menopause women

Protocol summary

Study aim

The comparison of the effect of acupuncture and drug therapy on hot flash and sleep disorders in menopausal women

Design

After obtaining written consent from eligible clients, individuals were randomly assigned based on randomly numbers table to two groups.

Settings and conduct

Acupuncture performed by a physician with acupuncture specialty. In the case group (acupuncture), acupuncture performed three times a week, each session took last for 20 minutes. Intervention duration were 4 weeks. Acupuncture points determined based on traditional Korean medicine, including ST36, SP6, L14, PC6, HT7, HT8, and a point at the bottom of the CV4 abdomen. A total of 7 points selected to reduce hot flashes. Subjects followed for 12 weeks after acupuncture. In the control group (routine care), fluoxetine administered for 4 weeks and subjects then followed for 12 weeks.

Participants/Inclusion and exclusion criteria

1 - Lack of menstruation at least in the past 12 months 2- Natural menopause 3. No history of ovarian surgery or hysterectomy 4- Lack of diabetes, migraine or receiving medication for any internal disorder

Intervention groups

Menopausal women with hot flash and sleep disorders

Main outcome variables

Evaluation of the frequency of hot flashes during day and night Evaluation of the severity of hot flashes during day and night

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171104037220N2**

Registration date: **2020-06-28, 1399/04/08**

Registration timing: **retrospective**

Last update: **2020-06-28, 1399/04/08**

Update count: **0**

Registration date

2020-06-28, 1399/04/08

Registrant information

Name

Tahereh Fathi Najafi

Name of organization / entity

Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 51 3225 0044

Email address

fathi_midwife@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-01-29, 1392/11/09

Expected recruitment end date

2017-12-31, 1396/10/10

Actual recruitment start date

2014-05-01, 1393/02/11

Actual recruitment end date

2019-12-31, 1398/10/10

Trial completion date

2020-01-21, 1398/11/01

Scientific title

The comparison of the effect of acupuncture and drug therapy on controlling hot flash and sleep disorders in menopause women

Public title

Acupuncture and menopausal disorders control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having adequate literacy to fill out the forms
Lack of menstruation at least in the past 12 months
Natural menopause
Experiencing at least 4 hot flashes during the day
No history of ovarian surgery
Confirmation of menopause with the help of hormonal testing and confirmation of $E2 < 18$ pg/ml, $FSH = 30-110$ IU/L
Lack of thyroid disorders and $TSH = 0.4-4$ IU/mL
Not using any over-the-counter herbal medicine based on doctor prescription to reduce hot flashes
Lack of diabetes, migraine or receiving medication for any internal disorder
Lack of chronic infections

Exclusion criteria:

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **82**

Actual sample size reached: **89**

Randomization (investigator's opinion)

Randomized

Randomization description

Menopausal women who referred to the Gynecology Clinic of Imam Reza Hospital due to hot flashes and were eligible to participate in the study based on inclusion and exclusion criteria randomly assigned to intervention and control groups based on random block allocation with a block size of 2. Each block stratified based on the frequency of hot flushed per day (less than 7 times and more than 7 times) and age at menopause (younger than 45 years old and older than 45 years old). Random allocation performed by assigning the first subject based on the frequency of hot flush per day to intervention or control group and assigning it's pair based on frequency of hot flush to the other group. This method ensured the similar allocation number in the study groups. To protect patients' rights, if the subjects did not like to continue acupuncture, they referred to the normal care.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of the Mashhad University of Medical Sciences

Street address

Daneshgah Avenue, Mashhad, Razavi Khorasan Province, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

91375345

Approval date

2014-01-29, 1392/11/09

Ethics committee reference number

IR.MUMS.REC.1393.44

Health conditions studied

1

Description of health condition studied

Hot flash and sleep disorders

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Evaluation of the frequency and severity of hot flashes

Timepoint

Before acupuncture, at the end of acupuncture period (4th week) and 12 weeks after acupuncture in the acupuncture group, before fluoxetine treatment, 4 weeks after treatment initiation and 12 weeks after treatment

Method of measurement

Severity of hot flash and Pittsburgh sleep disorder questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Acupuncture performed three times a week, each session took last for 20 minutes. Intervention duration was 4 weeks. Acupuncture points determined based on traditional Korean medicine, including ST36, SP6, L14, PC6, HT7, HT8, and a point at the bottom of the CV4 abdomen. A total of 7 points selected to reduce hot flashes. Metal disposable needles

used for the acupuncture in the mentioned points for 20 minutes. The length of the needles were 40 mm. The needles inserted 3-15 mm deep in the mentioned points.

Category

Treatment - Other

2**Description**

Control group: Were received fluoxetine for 4 weeks and subjects were then be followed for 12 weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam reza hospital

Full name of responsible person

Tahereh Fathi Najafi

Street address

Unit 9, No 55, 17 th Honarestan st

City

Mashhad

Province

Razavi Khorasan

Postal code

9178755114

Phone

+98 51 3868 7122

Email

fathi_midwife@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Leyla Porali

Street address

Goreshti biulding, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9179734688

Phone

+98 51 3841 2081

Email

pouralil@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**

Islamic Azad University

Full name of responsible person

Tahereh Fathi Najafi

Position

Assisstant Professore

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Dr Mohamad Shahinfar University, Sarab Bazarche, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9179734688

Phone

+98 51 3225 0044

Email

fathi_midwife@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Leyla Porali

Position

Associated Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Gham Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9179734688

Phone

+98 51 3859 1511

Email

pouralil@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Tahereh Fathi Najafi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Sarab Bazarcheh

City

Mashhad

Province

Razavi Khorasan

Postal code

9179734688

Phone

+98 51 3225 0044

Email

fathi_midwife@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not 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

Title and more details about the data/document

The comparison of the effects of acupuncture and drug therapy on controlling the frequency and severity of hot flashes among menopausal women

When the data will become available and for how long

From now to 6 months later

To whom data/document is available

Midwives, Obstetricians and gynecologist and acupuncturists

Under which criteria data/document could be used

Protocol and its results

From where data/document is obtainable

Tahereh fathi Najafi

What processes are involved for a request to access data/document

The request will be sent by email

Comments