Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
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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 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
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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

Islamic Azad University

Full name of responsible person

Tahereh Fathi Najafi

Position

Assisstant Professore

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Latest degree

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Person responsible for updating data

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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