Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of acupressure on the early menopausal complications in menopausal women who referred to selected health centers in Tehran 2012

Protocol summary

Summary

The purpose of this single blind placebo controlled randomized is to investigate the effect of acupressure on the early menopausal complications. Study population are include menopausal women who have hot flash and nigh sweat and anxiety and sleep quality disorders and are referred to selected public health centers in Tehran. the informed consent is obtained from patients. The patients will randomly assign in to intervention and placebo groups (n= 35 each). Intervention group receive (acupressure wrist band with push- button and education lifestyle changes during menopause) and placebo group receive (acupressure wrist band with out push- button and education lifestyle changes during menopause) for 4 weeks in the specific acupressure points (include Shenmen,Fuliu,Sanyinjiao) in wirst and ankle. Main out come measures are frequency and severity of hot flash and night sweating and severity of anxiety and sleep quality score wich measure by qustionnaires (Pittsburgh and Spielberger) and diary card for frequency and severity of hot flash and nigh sweat before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112278537N1**
Registration date: **2012-03-10, 1390/12/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-03-10, 1390/12/20

Registrant information

Name

Maryam Armand

Name of organization / entity

The International Branch of Shahid Beheshti University of Medical Sciences & Health services

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

The International Branch of Shahid Beheshti University of Medical Sciences & Health Services

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2012-06-14, 1391/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of acupressure on the early menopausal complications in menopausal women who referred to selected health centers in Tehran 2012

Public title

Acupressure and treatment the early menopausal complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Iranian nationality,being literate,age range 45-55 years,post menopausal females (elapsing 12 months of last menstural phase),not using acupressure,reporting at least two times hot flashes per day and having night sweat and anxiety and sleep quality disorders. Exclusion criteria: women who received hormon therapy during the last 6 months,having any known diseases such as diabetes,cardiovascular diseases,hypertention and thyroid diseases,having any known diseases in hand or foot,consumption of drugs such as sedative,alfa adrenergic agonist such as clonidin,supplements such as soya,vitamin E,cigarette smoking.

Age
From **45 years** old to **55 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The International Branch of Shahid Beheshti University of Medical Sciences & Health services

Street address
No 19,next to Shahid Hammat Bridge,vali asr street-Shahid Abaspoorst street,Tehran.

City
Tehran

Postal code

Approval date
2011-10-13, 1390/07/21

Ethics committee reference number
3743/116

Health conditions studied

1

Description of health condition studied
Early menopausal complications

ICD-10 code
N95.1

ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
The severity and frequency of hot flashes

Timepoint
A week before the study,end of second week,end of fourth week

Method of measurement
Diary card

2

Description
The severity and frequency of night sweat

Timepoint
A week before the study,end of second week,end of fourth week

Method of measurement
Diary card

3

Description
Severity of anxiety

Timepoint
Before the study,end of second week,end of fourth week

Method of measurement
Anxiety inventory spielberger

4

Description
Rating the quality of sleep

Timepoint
Before the study,end of second week,end of fourth week

Method of measurement
Pittsburgh sleep quality inventory

Secondary outcomes

1

Description
Quality of life

Timepoint
Before the study,end of fourth week

Method of measurement
Qality of life questionnaire

2

Description

Comparison of sleep quality score

Timepoint

Before the study,end of fourth week

Method of measurement

Pittsburgh sleep quality score

Intervention groups

1

Description

In the intervention group will be acupressure wrist band with push-button (for use Three times a week for 15 minutes) and education lifestyle changes during menopause.

Category

Treatment - Other

2

Description

In the control group will be acupressure wrist band with out push-button (for use Three times a week for 15 minutes) and education lifestyle changes during menopause.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centre Yaftabad

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Health centre Shadabad

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The International Branch of Shahid Beheshti University of Medical Sciences & Health services

Full name of responsible person

Dr. Ghanati, Research Manager

Street address

No 19,next to Shahid Hammat Bridge, vali asr street-Shahid Abaspoorst street,Tehran.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

The International Branch of Shahid Beheshti University of Medical Sciences & Health services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

The International Branch of Shahid Beheshti Univercity of Medical Sciences & Health services

Full name of responsible person

Maryam Armand

Position

Midwifery Master student of the International Branch of Shahid Beheshti University of Medical Scienc

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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The International Branch of Shahid Beheshti University of Medical Sciences & Health Services

Full name of responsible person

Giti Ozgoli

Position

Department of Midwifery, Faculty of Nursing-Midwifery Shahid Beheshty University of Medical Sciences

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person
Maryam Armand
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty