Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of electro-acupuncture in postmenopausal women with hot flashes

Protocol summary

Summary

The present study aimed to evaluate the effects of electro–acupuncture on hot flashes in postmenopausal women. In this randomized, placebo-controlled trial, 41 postmenopausal women with hot flashes were randomly assigned into intervention or control groups. In the intervention group, the electro-acupuncture was carried out while in the control group needles taped to the skin in the same acupoints without any electricity. The treatment period was 10 weeks then patients were followed for 3 months after the last session. The rate of hot flashes was recorded daily during 10 weeks treatment and 3 months follow-up periods. The severity of hot flashes was measured by VAS at the end of weeks 2, 6, and 10 after initiation of treatment and at the end of follow up period. Serum levels Follicle Stimulating Hormone (FSH) and Estradiol (E2) were measured at the end of 10 weeks treatment and 3 months follow-up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902222891N1**
Registration date: **2010-05-12, 1389/02/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-05-12, 1389/02/22

Registrant information

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Afsar Foroud
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Recruitment status

Recruitment complete

Funding source

Rasearch Center of Islamic Azad University of Kerman

Expected recruitment start date

2005-03-05, 1383/12/15

Expected recruitment end date

2006-02-04, 1384/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of electro-acupuncture in postmenopausal women with hot flashes

Public title

Acupuncture and Hot flashes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Average of 5 hot flashes per day, average severity of hot flashes of 3 or more on the VAS in two weeks before treatment, having a natural menopause of at least 6 months without medical or surgical interferences, healthy post-menopause women, age 49-62 years, not having previous experience of acupuncture, E2 <25 pg/ml, FSH>30 mlu/ml Exclusion criteria: Severe cardiovascular, metabolic, thromboembolic, endocrine, thyroid, or malignant diseases, uncontrolled hypertension, using hormone or medications interfering with vasomotor symptoms in 4

weeks prior to the study

Age
From **49 years** old to **62 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **41**

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
Kerman Islamic Azad University

Street address
First Kilometer of Jopar Road, Kerman-

City
Kerman

Postal code
7618644941

Approval date
2010-02-14, 1388/11/25

Ethics committee reference number
28702

Health conditions studied

1

Description of health condition studied
Hot flashes in postmenopause women

ICD-10 code
N95.1

ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
Number of hot flashes

Timepoint
Two weeks before treatment, daily during 10 weeks treatment, weekly during 3 months after the last treatment

Method of measurement
a self-report hot flash diary

2

Description
hormon levels of E2 and FSH

Timepoint
Baseline, at the end of 10 weeks treatment and 3 months after the last treatment.

Method of measurement
laboratory kits

3

Description
Severity hot flashes

Timepoint
baseline, weeks 2, 6, and 10 and 3 months after the end of therapy

Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Needles taped to the skin in the same acupoint without any electricity

Category
Treatment - Other

2

Description
The electro-acupuncture was carried out in the menopause acupoint

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Gynecological Clinics of Kerman

Full name of responsible person
Masoumeh Nakhei

Street address
Kashani Hospital, Abohamed Street

City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman Islamic Azad University
Full name of responsible person
Dr. Kazemipour
Street address
First Kilometers of Jopar Road, Islamic Azad University
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman Islamic Azad University
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

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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