

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Comparison of accupressure's effect at points k1 and LI4 on hot flashing of menopausal women referred to selective clinics affiliated to hospitals of Shiraz University of Medical Sciences 2012-2013

#### Protocol summary

2013-07-21, 1392/04/30

#### Summary

The purpose of the study and study design: Comparison of effect two points of accupressure's points on hot flashing of menopause women - random - not blinded - placebo not used. The study population: volunteers 45-55 years and eligible for inclusion - The main criteria for inclusion: age 55-45 years; passing at least a year after the last menstrual; not having the disease, high blood pressure and cardiovascular diseases; flushing severity scores higher than 5 with VAS criteria; not receiving hormonal and non-hormonal drugs complementary medicine. The main exclusion criteria: unwillingness to cooperate; chemotherapy or radiotherapy and the need for taking any medication during the study. Sample: The study population was selected from among 90 eligible and they randomly divided into three groups of 30(k1 - li4 and control). Intervention: accupressure therapy sessions (10 sessions over 5 weeks) In 2 Groups k1 and li4 and control group (not intervention) completed questionnaires: early intervention and after 6 weeks in all three groups. Outcome Study: Comparison of accupressure's effect within two points K1 and LI4 on three variables (intensity, duration and frequency) hot flashing of menopause women.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013062513770N1**  
Registration date: **2013-07-21, 1392/04/30**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

#### Registrant information

##### Name

fatemeh zeinaly khozany

##### Name of organization / entity

shiraz university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1647 4255

##### Email address

zeinali@sums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Research office of Shiraz University Of Medical Sciences

#### Expected recruitment start date

2013-06-20, 1392/03/30

#### Expected recruitment end date

2013-10-22, 1392/07/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of accupressure's effect at points k1 and LI4 on hot flashing of menopausal women referred to selective clinics affiliated to hospitals of Shiraz University of Medical Sciences 2012-2013

#### Public title

Comparison of effect two points of accupressure's points on hot flashing of menopausal women

#### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: not receiving hormonal and non-hormonal drugs in the last 6 months; did not have cardiovascular disease at 6 months; flushing severity scores higher than 5 with VAS criteria; age 55-45 years old; passing at least one year of amenorrhea; non-smoking; not having hypertension; no abnormal vaginal bleeding; do not use other forms of complementary medicine; lack of diabetic foot ulcers(contraindications pressure on k1 point); not hysterectomy; not thrombophlebitis or not mass near acupressure region; not amputation of limbs. Exclusion criteria: lack of willingness to cooperate; the need to Chemotherapy or radiation therapy during the study; diagnose any illness and need to take any medication during the study and amputation of limbs.

### **Age**

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

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **90**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **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**

Ethics committee of Shiraz University Of Medical Sciences

##### **Street address**

Shiraz, Zand Ave, Shiraz University of Medical Science Building

##### **City**

SHIRAZ

##### **Postal code**

7193613119

#### **Approval date**

2013-06-09, 1392/03/19

#### **Ethics committee reference number**

CT-92-6555

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

hot flash

#### **ICD-10 code**

N95.1

#### **ICD-10 code description**

Symptoms such as flushing, sleeplessness, headache, lack of concentration, associated with menopause

## **Primary outcomes**

### **1**

#### **Description**

Severity of hot flushes

#### **Timepoint**

Early intervention and after 6 weeks in all three groups.

#### **Method of measurement**

Questionnaire and visual analog scale(vas)pain

### **2**

#### **Description**

Frequency of hot flash

#### **Timepoint**

Early intervention and after 6 weeks in all three groups

#### **Method of measurement**

Questionnaire

### **3**

#### **Description**

Flushing time

#### **Timepoint**

Early intervention and after 6 weeks in all three groups.

#### **Method of measurement**

Questionnaire

## **Secondary outcomes**

### **1**

#### **Description**

Improve hot flush

#### **Timepoint**

After intervention

#### **Method of measurement**

Questionnaire and visual analog scale pain

## **Intervention groups**

### **1**

#### **Description**

intervention group: Acupressure session for 10 sessions over 5 weeks in group li4

#### **Category**

Treatment - Other

## 2

### Description

intervention group: Acupressure session for 10 sessions over 5 weeks in group k1

### Category

Treatment - Other

## 3

### Description

control group : :Without intervention

### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Motahari Clinic

##### Full name of responsible person

##### Street address

Namazi square, Shiraz

##### City

SHiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for Research, Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Gholam Reza Hatam

##### Street address

7th Flat, Central department of Shiraz University of Medical Sciences, Zand Street, Shiraz

##### City

Sliraz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for Research, Shiraz University of Medical Sciences

#### 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

Fatemeh (PBUH) College of Nursing and Midwifery

#### Full name of responsible person

Azam Jokar

#### Position

Faculty Member, MSc in Midwifery

#### Other areas of specialty/work

#### Street address

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Student, MSc in Midwifery

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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*