

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Investigation the effect of acupressure on pain, stiffness and physical function of elderly with knee osteoarthritis

#### Protocol summary

##### Study aim

The survey of effect LI 4, SP10, SP9, GB34, ST36, ST34 acupressure on severity of knee pain caused by osteoarthritis in the elderly living in the city of Rafsanjan city in 2017

##### Design

The samples were categorized into three intervention, control and touch group by using stratified randomization method (minimization). The target classes were gender-based. Then the samples were randomly assigned (lottery) to the groups.

##### Settings and conduct

This study is a randomized clinical trial. And place of the research is all health centers in Rafsanjan

##### Participants/Inclusion and exclusion criteria

Patients with osteoarthritis in one or both knees Age over 60 years old Having informed consent to participate in the study

##### Intervention groups

Acupressure intervention is performed by a researcher for three one hour training sessions training sessions for the elderly of the intervention group. Acupressure in this study is pressure applied at the points LI 4, SP10, SP9, GB34, ST36, ST34.

##### Main outcome variables

Reduce pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180114038366N1**

Registration date: **2018-04-13, 1397/01/24**

Registration timing: **retrospective**

Last update: **2018-04-13, 1397/01/24**

Update count: **0**

##### Registration date

2018-04-13, 1397/01/24

##### Registrant information

###### Name

Tahere Norozi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3428 8625

###### Email address

taherenorozi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-11-22, 1396/09/01

##### Expected recruitment end date

2018-02-20, 1396/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigation the effect of acupressure on pain, stiffness and physical function of elderly with knee osteoarthritis

##### Public title

The effect of acupressure on pain, stiffness and physical function of elderly with knee osteoarthritis

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Not receiving any supplemental or alternative treatment for osteoarthritis during the last three months Dont have

any history of using acupressure for any purpose The absence of any scars, scratches and deformities at points LI 4, SP10, SP9, GB34, ST36, ST34 Ability to speak and understand Persian language Having enough power of visual and auditory Do not use anticoagulants or any coagulation disorder Dont have history of surgery associated with the disease (such as replacement and joint repair) on the joint Having osteoarthritis in one or both diapers for at least three months based on the clinical criteria of the American College of Rheumatology BMI below 40. Having a phone line to track Aged over 60 years Having informed consent to participate in the study Not having advanced neuropathy Non-addiction and lack of chronic use of opiates Failure to inject injections into the knee joint or arthroscopy within 30 days prior to intervention Having enough cognitive and functional strength to learn and implement the intervention Lack of history of topical skin lesions and open wounds in acupressure areas, other autoimmune diseases, including lupus erythematosus, have chronic neuropathic conditions such as diabetes.

**Exclusion criteria:**

Having previous history of acupressure Reduced level of consciousness Patients who do not cooperate for any reason until the end of the intervention Patients who have acute pressure at the points LI4, SP10, SP9, GB34, ST36, ST34 have no feeling of warmth, heaviness, swelling or anesthesia at this point Unwillingness to cooperate with each research unit during the study Injection of housing into the knee joint during the intervention period Those who need to receive housing during the intervention until the second and third assessment of the severity of pain. Lower limb and upper limb Having mental illness during the intervention period

**Age**

From **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **96**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Factorial

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Rafsanjan University of Medical Sciences

**Street address**

Ali ibn Abitaleb Hospital - Imam Ali Blvd - Head Office of Rafsanjan University of Medical Sciences

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717933777

**Approval date**

2017-12-12, 1396/09/21

**Ethics committee reference number**

IR.RUMS.REC.1396.121

**Health conditions studied**

1

**Description of health condition studied**

Osteoarthritis

**ICD-10 code**

M17.9

**ICD-10 code description**

Osteoarthritis of knee, unspecified

**Primary outcomes**

1

**Description**

pain

**Timepoint**

21 day

**Method of measurement**

WOMAC questionnaire

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group 1: Acupressure at LIV3 LI11, LI4 and ST 36 points.

**Category**

Rehabilitation

2

**Description**

Intervention group 2: Only touch without pressure at,

LIV3 LI11, LI4 and ST 36.

**Category**

Rehabilitation

**3**

**Description**

Control group: This group did not receive any acupressure treatment

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Health centers in Rafsanjan

**Full name of responsible person**

Ali Mozafari

**Street address**

Ali Ibn Abitaleb Hospital, Mofatat Blvd, Rafsanjan-

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AMOZAFARI2001@Yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Ali Shamsizadeh

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University Headquarters, Imam Ali Blvd, Rafsanjan

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alishamsy@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Rafsanjan 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**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Ali Ansari Jaberi

**Position**

Academic instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Position**

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**Latest degree**

Master

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**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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