

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of self- acupressure on the pain and physical function of patients with knee osteoarthritis

#### Protocol summary

##### Study aim

1- Comparison of pain before and after intervention in two groups of intervention and control. 2- Comparison of pain intensity before and after intervention in two groups of intervention and control. 3- Comparison of dry joints before and after intervention in intervention and control groups. 4. Comparison of physical function before and after intervention in two groups of intervention and control. 5- Comparison of pre-and post-intervention drug use in both intervention and control groups.

##### Design

The sample size is based on Table B.12 1 for the comparison of the mean of the three independent groups (control, conventional treatment, acupressure).

##### Settings and conduct

Samples were collected from patients referring to the Imam Khomeini Hospital clinic as well as orthopedic clinics. Following the training, weekly follow up is done on the intervention and the results.

##### Participants/Inclusion and exclusion criteria

1- The severity of the pain in the knee is based on a scale of over 3. 2. Not using other complementary therapies or relaxation techniques such as yoga and relaxation and ... 3. No knee injury that prevents acupressure in that area 4. Failure to develop a disease of rheumatoid arthritis or lupus that may cause symptoms such as osteoarthritis.

##### Intervention groups

Patients are randomly assigned into three independent groups (control and conventional therapy and acupressure). The training is given to the intervention group during the same session in person. The acupressure training is also given to the control group, with the difference that we introduce the pressure points at a distance of 1 cm from the main points. At the end of the study, acupressure training will be given to the control group..

##### Main outcome variables

Acupressure; pain; pain intensity; physical function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181217042032N1**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

##### Registration date

2019-03-09, 1397/12/18

##### Registrant information

##### Name

Lale Raygan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3337 7864

##### Email address

raygan.l@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-20, 1397/12/01

##### Expected recruitment end date

2019-05-22, 1398/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of self- acupressure on the pain and physical function of patients with knee osteoarthritis

**Public title**

The effect of acupressure on osteoarthritis

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age group 50-70 years Diagnosis of knee osteoarthritis by orthopedics or physical medicine Sudden acute pain in the patient based on high and high scales. Not using other therapeutic or tranquil methods such as relaxation such as yoga and relaxation and ... Lack of knee injury that prevents surgical procedures in that area Non-development of rheumatoid arthritis or liposoma that shows symptoms like osteoarthritis Ability to learn and implement intervention.

**Exclusion criteria:**

Need surgery during intervention.

**Age**

From **50 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **78**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The method of assigning intervention to individuals was randomized and random blocked blocks with a block size of 6 according to the objectives of the study, the researcher's opinion, previous studies and taking into account the parameters  $\alpha = 0.01$ , power = 0.9 and (low difference) The highest and most mean score of pain was calculated based on Womac =  $\Delta$  and standard deviation of pain score =).

**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**

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

**Street address**

No 69 ; west 17 Ave; kianpars

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

۶۱۵۵۸۸۷۸۸۸

**Approval date**

2018-10-20, 1397/07/28

**Ethics committee reference number**

IR.AJUMS.REC.1397.539

**Health conditions studied****1****Description of health condition studied**

Knee osteoarthritis

**ICD-10 code**

M17

**ICD-10 code description**

Osteoarthritis of knee

**Primary outcomes****1****Description**

Percentage of physical function of patients with knee osteoarthritis based on womak questionnaire

**Timepoint**

The beginning of the study; 4 weeks after the start of the study and 8 weeks after the start of the study

**Method of measurement**

visual Analogue Scale . Womak

**Secondary outcomes****1****Description**

Patient Physical Performance Score

**Timepoint**

Beginning of study. 4 weeks after the start of the study and 8 weeks after the start of the study

**Method of measurement**

Visual Analogue Scale - Womak questionnaire

**Intervention groups****1****Description**

Intervention group: In this group, acupressure intervention is taught to patients on 5 specific points around the knee and patients are asked to take interventions every day on the trained points. The assessment will be performed on the start of the study and 4 weeks after the start and 8 weeks after the start of the study.

**Category**

Rehabilitation

**2****Description**

Intervention group: Intervention group training is also given to this group, with the difference that the acupressure points are introduced and trained by a 1 cm difference.

**Category**

Rehabilitation

**3****Description**

Control group: This group is without training and in the same conditions as before entering this study.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Clinic of Imam Khomeini Hospital

**Full name of responsible person**

Laleh Raygan

**Street address**

24 meters high street. Imam Khomeini Hospital

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6155887888

**Phone**

+98 61 3337 7864

**Email**

www.l.raygan79@gmail.com

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

mojgan javad noory

**Street address**

Golestan Main Blvd. Jundishapur University

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715794

**Phone**

+98 61 3337 7864

**Email**

l.raygan79@gmail.com

**Web page address****Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Laleh Raygan

**Position**

Senior Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No 69. West 17th Street. Kianpars

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6158887888

**Phone**

+98 61 3337 7864

**Email**

www.l.raygan79@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Laleh Rayegan

**Position**

Senior Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

no 69. West 17th Street.Kianpars

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6155887888

**Phone**

+98 61 3337 7864

**Email**

www.l.raygan79@gmail.com

+98 61 3337 7864

**Email**

www.l.raygan79@gmail.com

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data of the participants will be shared after unauthorized identification.

**When the data will become available and for how long**

Get started since 1400

**To whom data/document is available**

For researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

If used and completed, research is available.

**From where data/document is obtainable**

www. l.raygan79@gmail.com

**What processes are involved for a request to access data/document**

Approximately 2-3 weeks after receiving the email.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Laleh Rayegan

**Position**

Senior Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No 69. West 17th Street. Kianpars

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6158887888

**Phone**