

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The effectiveness of dry needling on scar tissue: a randomized controlled trial

#### Protocol summary

##### Study aim

Investigating the therapeutic effects of dry needling on the complications resulting from linear hypertrophic scars caused by surgery or trauma.

##### Design

This study will be a single-blind, randomized, two-arm, parallel-group, sham-controlled trial with a 1:1 allocation ratio. Patients will be randomly assigned to either the intervention or control group using the permuted block randomization method.

##### Settings and conduct

Participants will be randomly assigned to intervention or control groups using permuted randomization. A third-party will create a random treatment list and place it in sequentially numbered envelopes. The envelopes will be given to participants after their primary assessment. The study will take place at the School of Rehabilitation Sciences, IUMS, and Bethesda, USA.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Linear hypertrophic scar tissue with an age of more than six weeks. 2- No restrictions on active and passive joint range of motion near the scar tissue. 3- Age between 20-60 years. Exclusion criteria: 1- Needle phobia 2- Immature scar or keloid scar 3- Skin diseases or infections near the scar tissue 4- Diabetes 5- Fractures that have altered joint mobility 6- Anticoagulant medication use.

##### Intervention groups

The main intervention group will receive dry needling therapy with 2 cm needles inserted at an angle of approximately 15 degrees into the scar tissue and rotated to release tissue adhesions. Dry needling will be performed along the length of the scar. The control group will receive needles of the same dimensions inserted into a location further away from the scar tissue on the same limb, without any movement, and removed after 20 minutes. Both primary treatment groups will also receive a baseline treatment of ten minutes of infrared therapy and kinesiology taping of the scar tissue.

#### Main outcome variables

The flexibility of the scar tissue

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130409012953N4**

Registration date: **2023-08-21, 1402/05/30**

Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**

Update count: **0**

##### Registration date

2023-08-21, 1402/05/30

##### Registrant information

##### Name

Mohammadreza Pourahmadi

##### Name of organization / entity

Rehabilitation Research Center, Department of Physiotherapy

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 2059

##### Email address

pourahmadipt@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2024-02-20, 1402/12/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of dry needling on scar tissue: a randomized controlled trial

**Public title**

Effect of dry needling in treatment of scar

**Purpose**

Treatment

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

Longitudinal scar tissue older than six weeks No contraindication for joint active and passive movements near the scar tissue Age between 20-60 years

**Exclusion criteria:**

Trypanophobia Skin problems (such as infection, wounds, atopic dermatitis)

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

All eligible patients with hypertrophic scar tissue will be randomized to an intervention group (dry needling in addition to routine physical therapy) and a control group (sham dry needling in addition to routine physical therapy) with a ratio of 1:1. Randomized allocation will be performed by using permuted block randomization method, which consists of four-letter blocks made of letters A and B. Then, the random treatment list that will be obtained at the end of the random allocation task will be placed in letters A and B inside the sealed and numbered envelopes (A letter indicates true dry needling and letter B indicates sham dry needling). Six four-letter blocks of letters A and B will be created in which the letter A or B is not repeated more than twice in each block. These blocks include AABB, ABAB, BBAA, BAAB, ABBA, BABA. Considering that each block represents 4 participants and in the current study, 80 participants are needed, 20 blocks of four are required. Referring to a table of 20 random numbers between 1 to 6 (the number of blocks created above), the selection process will be performed using Google Random Number Generator. The random assignment process will be performed by someone outside the research team before the study begins. After the initial evaluation of the patient by the examiner, the numbered envelopes will be presented to him/her according to the ordinal number of each person

admitted to the study. Finally, after each patient enters the treatment sessions, the therapist will adjust the treatment interventions based on the letters in the envelope. Patients are asked not to provide their grouping information to the assessor to prevent data contamination.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Individuals in the control group will be in the same position as those in the intervention group, with needles placed superficially in an area slightly further away from the scar tissue. Additionally, the data analyst will be unaware of the grouping of the participants, and each participant will be identified by a unique numerical code.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Madadkaran (Nezam) St., Shahnazari St., Madar Sq., Mirdamad Blvd. Tehran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1545913487

**Approval date**

2022-08-27, 1401/06/05

**Ethics committee reference number**

IR.IUMS.REC.1401.455

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

Scar tissue

**ICD-10 code**

L90.5

**ICD-10 code description**

Scar conditions and fibrosis of skin

**Primary outcomes**

## 1

### **Description**

The flexibility of the scar tissue

### **Timepoint**

At the start of the study (prior to the intervention), immediately following the final treatment session, and two weeks after the completion of the treatment sessions.

### **Method of measurement**

Tissue compliance meter

## **Secondary outcomes**

## 1

### **Description**

Active and passive joint range of motion

### **Timepoint**

At the start of the study (prior to the intervention), immediately following the final therapy session, and two weeks after the completion of the treatment sessions.

### **Method of measurement**

Universal goniometer

## 2

### **Description**

Pain

### **Timepoint**

At the start of the study (prior to the intervention), immediately following the final therapy session, and two weeks after the completion of the treatment sessions.

### **Method of measurement**

Numeric pain rating scale

## 3

### **Description**

Functional disability

### **Timepoint**

At the start of the study (prior to the intervention), immediately following the final therapy session, and two weeks after the completion of the treatment sessions.

### **Method of measurement**

SF-36 questionnaire

## **Intervention groups**

## 1

### **Description**

Intervention group: Dry needling therapy in the true dry needling group along with routine physiotherapy is performed by inserting a 2 cm Dung bang brand needle at an angle of about 15 degrees to the skin surface into the scar tissue and rotating it to separate the tissue adhesions. This is done along the path of the scar. The number of treatment sessions for patients is 6 sessions, which will be performed 3 sessions per week for two weeks. The assessment of participants will be done once before starting the treatment, immediately after the end of the treatment, and two weeks after the last treatment

session. Routine physiotherapy treatment for patients with scars in both groups includes using kinesiology taping along with infrared (for 20 minutes) at a distance of 30 cm from the scar tissue.

### **Category**

Rehabilitation

## 2

### **Description**

Control group: In the sham dry needling treatment group along with routine physiotherapy, the patient's condition is completely similar to the real dry needling treatment group, except that instead of a real needle, a sham needle is used. The needle is inserted superficially at a point further away from the scar tissue and is removed after 20 minutes. Routine physiotherapy in this group is similar to the main intervention group.

### **Category**

Placebo

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

School of Rehabilitation Sciences of Iran University of Medical Sciences

#### **Full name of responsible person**

Mohammadreza Pourahmadi

#### **Street address**

Madadkaran (Nezam) St., Shahnazari St., Madar Sq., Mirdamad Blvd. Tehran.

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1545913487

#### **Phone**

+98 21 4426 5033

#### **Email**

pourahmadipt@gmail.com

## 2

### **Recruitment center**

#### **Name of recruitment center**

Myopain Seminars

#### **Full name of responsible person**

Jan Dommerholt

#### **Street address**

4405 East-West Highway, Suite 401 Bethesda, MD 20814-4522

#### **City**

Bethesda

#### **Postal code**

20814-452

#### **Phone**

+1 855-209-1832

#### **Email**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Deputy of Research of Iran University of Medical Sciences

**Full name of responsible person**

Mohammadreza Pourahmadi

**Street address**

Madadkaran All., Shahnazari St., Madar Sq., Mirdamad Blvd., Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

4391-15875

**Phone**

+98 21 2222 2059

**Email**

pourahmadipt@gmail.com

**Grant name****Grant code / Reference number**

1400-2-99-21572

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

Yes

**Title of funding source**

Deputy of Research of Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Mohammadreza Pourahmadi

**Position**

Assistant professor

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

Madadkaran (Nezam) St., Shahnazari St., Madar Sq., Mirdamad Blvd. Tehran.

**City**

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**Province**

Tehran

**Postal code**

1545913487

**Phone**

+98 21 2222 2059

**Email**

pourahmadipt@gmail.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mohammadreza Pourahmadi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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+98 21 2222 2059

**Email**

pourahmadipt@gmail.com

## Person responsible for updating data

**Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mohammadreza Pourahmadi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Madadkaran All., Shahnazari St., Madar Sq., Mirdamad Blvd., Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1545913487

**Phone**

+98 21 2222 2059

**Fax**

+98 21 2222 2059

**Email**

pourahmadipt@gmail.com

## Sharing plan

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

Yes - There is 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

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

The raw data of research and its analysis will be available to the researcher if they request it.

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

After six months from the date of publication.

**To whom data/document is available**

The data will be available for physical therapists working in academic institutions and also clinicians working in the field of dry needling.

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

The raw data and results of this study can be used in future relevant systematic reviews. Thus, the raw data and results of this study will be available for researchers working in the field of dry needling.

**From where data/document is obtainable**

Applicants can contact Dr. Mohammad Reza Pourahmadi by email. Email address: pourahmadipt@gmail.com

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

Applicants should explain in detail about their project and how the data/documents of this study will be used in their project. Then, the data/documents files will be sent by email to applicants on request. This process may takes 10-12 working days.

**Comments**