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
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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.
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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
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Sponsors / Funding sources

1

Sponsor
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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
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Person responsible for updating data

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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