Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the effect of electromagnetic therapy to reduce pain and disability in patients with shoulder impingement syndrome

Protocol summary

Study aim
The effect of magnet therapy in reducing pain and disability and increasing range of motion in patients with shoulder impingement syndrome will be evaluated.

Design
Clinical trial with control group, with factorial groups, double blind, randomized, phase 3 on 60 patients, block randomization with stata software is used for randomization.

Settings and conduct
This study is performed in Tabriz rehabilitation clinic. Among the patients referred, 60 patients were randomly divided into 3 groups, including the group of magnetic therapy with a frequency of 18 Hz, the group of magnetic therapy with a frequency of 100 Hz and the group of control. Participants and evaluators in this study are blind and randomized and then treated by another person.

Participants/Inclusion and exclusion criteria
Patients in their 20s and 60s who have had pain in the shoulder joint for at least one month and have at least one active shoulder movement restricted. They also do not have neck, elbow or hand injuries, neurological disorders, rheumatoid arthritis, or previous upper extremity surgery and are not pregnant.

Intervention groups
The study consists of 3 groups. All 3 groups receive conventional electrotherapy and exercise therapy. Patients receive 12 sessions of magnet therapy. In the Sham group as a placebo and in the other two groups the intensity and duration of each session are the same and the difference between the two groups is in the frequency of the magnet, which is 18 Hz in one and 100 Hz in the other.

Main outcome variables
Before starting treatment, pain is measured using a visual analog scale (VAS), disability is assessed using a pain and disability questionnaire (including the DASH(Disabilities of the Arm, Shoulder and Hand)), and shoulder range of motion is measured using a goniometer.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210424051069N1**
Registration date: **2021-05-30, 1400/03/09**
Registration timing: **prospective**

Last update: **2021-05-30, 1400/03/09**
Update count: **0**

Registration date
2021-05-30, 1400/03/09

Registrant information

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Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-06-10, 1400/03/20
Expected recruitment end date
2021-10-22, 1400/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of electromagnetic therapy to reduce pain and disability in patients with shoulder impingement syndrome

Public title
The effect of magnet therapy in the treatment of patients with shoulder impingement syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who have pain in the shoulder joint for at least one month. There should be restrictions on at least one active shoulder movement (flexion, abduction, external and internal rotation). Participants are in the age range of 20 to 60 years. Get an initial DASH score of more than 45%.

Exclusion criteria:
Participants with neurological disorders. Participants with injuries to the neck, elbows or hands. Participants with rheumatoid arthritis. Participants with heart disease. Participants who have a history of previous upper limb surgery. Women who are pregnant. People who have received intra-articular anti-inflammatory drugs in the last 60 days. Participants with pathological shoulder disorders such as hooked acromion, osteoarthritis, adhesive capsulitis or traumatic labrum tears.

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to 3 treatment groups. The size of the blocks will be 6 and 9. Random block allocation will be done with stata software. Concealment or allocation cover will be done using the technique of closed and opaque envelopes, so that the treatment group of eligible patients who are randomly assigned to the study will be placed in closed and opaque envelopes, respectively. In the order in which patients enter the study, the envelope corresponding to each person's entry number will be opened and he will receive the assigned treatment.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and evaluators in this study are blind. Randomization and treatment is done by another person.

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Faculty of Rehabilitation Sciences, next to Vahdat Hall, University of Tabriz, 29 Blvd.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2021-04-24, 1400/02/04

Ethics committee reference number
IR.TBZMED.REC.1400.055

Health conditions studied

1

Description of health condition studied
Shoulder impingement syndrome

ICD-10 code
M75.4

ICD-10 code description
Impingement syndrome of shoulder

Primary outcomes

1

Description
Pain, disability, shoulder range of motion

Timepoint
Measurement of pain, disability and shoulder range of motion at the beginning of the study (before the intervention) and after the end of treatment sessions (12th session)

Method of measurement
Visual Analogue Scale; Disabilities of the Arm, Shoulder and Hand questionnaire; Goniometer

Secondary outcomes

1

Description
Gender, age, height, weight, occupation, hand dominance
Timepoint
Before the intervention
Method of measurement
Questionnaire, meter, Weighing scale

Intervention groups

1

Description
The first intervention group: magnet therapy with a frequency of 18 Hz, Magnet therapy is 12 sessions, 3 times a week for 4 weeks. The magnitude of the magnet is 100 mT and the duration of each treatment session is 30 minutes, but the frequency is set at 18 Hz in this group. They also receive conventional electrotherapy and exercise therapy.
Category
Rehabilitation

2

Description
The second intervention group: magnet therapy with a frequency of 100 Hz, Magnet therapy is 12 sessions, 3 times a week for 4 weeks. The magnitude of the magnet is 100 mT and the duration of each treatment session is 30 minutes, but the frequency is set at 100 Hz in this group. They also receive conventional electrotherapy and exercise therapy.
Category
Rehabilitation

3

Description
Control group: Placebo magnet therapy. Magnet therapy 12 sessions, 3 times a week for 4 weeks as a placebo. They also receive conventional electrotherapy and exercise therapy.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Comprehensive Rehabilitation Specialized Clinic
Full name of responsible person
Zahra Afzalifard
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
1
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
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mirali Eterafoskouei

Position
Professor
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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
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
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
Title and more details about the data/document
Information about the main data including pain intensity, questionnaire score, range of motion can be shared
When the data will become available and for how long
One month after completing the data analysis
To whom data/document is available
Scientific and academic researchers
Under which criteria data/document could be used
In order to design similar new studies
From where data/document is obtainable
Eterafoskouei@tbzmed.ac.ir Zahra.Afzalifard@gmail.com
What processes are involved for a request to access data/document
Full details about the use of the requested documents will be sent to the mentioned e-mail address and if approved, it will be available as soon as possible.
Comments