

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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

Name

zahra Afzalifard

Name of organization / entity

Country

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

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

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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

Sponsor

Name of organization / entity

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Full name of responsible person

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Web page address

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

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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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