

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Evaluating the effect of Tecar therapy on shoulder passive Range of Motion and Shoulder Pain and Disability Index in patients with frozen shoulder

Protocol summary

Study aim

The results of this study may help to improve the therapeutic quality of Frozen Shoulder patients and determine which of the two standard physiotherapy and Tecar therapy can improve the shoulder range of motion and Shoulder Pain and Disability Index in these patients. It also can help physiotherapists choose the most effective treatment for frozen shoulder patients.

Design

Double blind RCT, with control and intervention group, with sample size of 15 patient in each group. Grouping is done randomly through the random number table.

Settings and conduct

The study is being conducted in a private physiotherapy clinic. All participants are evaluated for passive shoulder range of motion by Inclinator and for shoulder pain and disability index by this questionnaire before, one day after and 4 weeks after the end of treatments. Participants and assessor are blind of the type of treatment and treatment groups.

Participants/Inclusion and exclusion criteria

Participants in this study are male and female patients with frozen shoulder between 41 to 72 years old, with shoulder pain and movement limitation for at least 3 months, and the limitation of passive external rotation of the shoulder greater than 30 degree compared to the contralateral side. Patients with bilateral frozen shoulder and those with systemic inflammatory diseases, malignancies, complete rotator cuff tear, history of shoulder joint surgery and ... are excluded from this study.

Intervention groups

In this study, both control and intervention groups receive 8 session of standard physiotherapy treatment; consisting of continuous ultrasound and TENS over the shoulder joint and home exercise program. The intervention group will receive 10 minute Tecar therapy

at the end of each session following standard physiotherapy.

Main outcome variables

Shoulder Pain and disability Index; Passive shoulder range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191130045550N1**

Registration date: **2020-01-07, 1398/10/17**

Registration timing: **prospective**

Last update: **2020-01-07, 1398/10/17**

Update count: **0**

Registration date

2020-01-07, 1398/10/17

Registrant information

Name

Maryam Raeisi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-15, 1398/12/25

Expected recruitment end date

2020-11-10, 1399/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of Tecar therapy on shoulder passive Range of Motion and Shoulder Pain and Disability Index in patients with frozen shoulder

Public title

Evaluating the effect of Tecar therapy in patients with frozen shoulder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male and female patients with Frozen Shoulder between 41 and 72 years of age Shoulder pain and movement limitation of minimum 3 months duration Restriction of passive external rotation more than 30° in the glenohumeral joint compared to the contralateral side Restriction of passive motion of at least a second plane of movement more than 30° in the glenohumeral joint compared to the contralateral side Have enough ability to fill out the questionnaire

Exclusion criteria:

Bilateral Frozen shoulder Systemic inflammatory joint disease like Rheumatoid arthritis, psoriasis arthritis and ... Malignancies Medical conditions such as cardiac diseases, infections and coagulation disorders Full thickness tear of rotator cuff History of shoulder joint surgery Neurological disorders of the upper limb Osteoarthritis of the glenohumeral joint Fractures of upper limb Cervical radiculopathy Impaired sensation of hot and cold Subjects who had a cardiac pacemaker Pregnancy Subjects who had physiotherapy treatment in the past 6 weeks Taking analgesic or anti-inflammatory drugs

AgeFrom **41 years** old to **72 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

Half of all sample numbers will be randomly selected from the random number table to form Group 1 and the remaining numbers will be Group 2.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are blind to which of the two intervention control groups. The person evaluating the data is a person other than the researcher and is kept blind and unaware of the treatment group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Isfahan University of Medical Sciences

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Hezar jerib Ave., Isfahan University Of Medical Sciences, Isfahan, Iran

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Province

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Postal code

0000081746

Approval date

2019-11-12, 1398/08/21

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.447

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

Frozen shoulder

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

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

Shoulder joint passive range of motion

Timepoint

Before treatment, 1 days after last session, 4 weeks after treatment

Method of measurement

Digital inclinometer

2**Description**

Shoulder Pain and Disability Index
Timepoint
Before treatment, 1 days after last session, 4 weeks after treatment
Method of measurement
shoulder pain and disability index Questionnaire

Secondary outcomes

empty

Intervention groups

- 1
- Description**
Intervention group: Standard physiotherapy and Tecar therapy, 8 session every other day, including 5 minute continuous ultrasound on the shoulder joint, 20 minute TENS on the shoulder joint, therapeutic exercise, Tecar therapy 10 minute on the shoulder joint
- Category**
Rehabilitation
- 2
- Description**
Control group: Standard physiotherapy, 8 session every other day, including 5 minute continuous ultrasound on the shoulder joint, 20 minute TENS on the shoulder joint, therapeutic exercise
- Category**
Rehabilitation
- Recruitment centers**
- 1
- Recruitment center**
- Name of recruitment center**
Tan Aram Private physiotherapy clinic
- Full name of responsible person**
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sh_haghjoo@med.mui.ac.ir
- Grant name**
- Grant code / Reference number**
- Is the source of funding the same sponsor organization/entity?**
Yes
- Title of funding source**
Esfahan 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**
Esfahan University of Medical Sciences
- Full name of responsible person**
Maryam Raeisi
- Position**
MSc student
- Latest degree**
Bachelor
- Other areas of specialty/work**
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- Sponsors / Funding sources**
- 1
- Sponsor**

Person responsible for scientific inquiries

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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

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 potential data is shared after unidentifiable people.

When the data will become available and for how long

Start of access period from 2021

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

No conditions

From where data/document is obtainable

Maryam Raeisi, email address:
maryam.raeisi92@gmail.com

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

Send request email, explain purpose and how data is used, be bound by complete information protection and ethics in research

Comments