Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Inclinometer 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)

Phone

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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
Age
From **41 years** old to **72 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target 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
Street address
Hezar jerib Ave., Isfahan University Of Medical Sciences, Isfahan, Iran
City
Isfahan
Province
Isfehan
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

Maryam Raeisi

Street address

Unit 2, Elahieh Complex, Shahid Turki Alley, Sohrevardi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh HaghJoo Javanmard

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Building 4, Hezar Jarib Street, Isfahan University of Medical Sciences

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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

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

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
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