Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of thecarotherapy on the range of motion in patients with frozen shoulder

Protocol summary

Study aim
evaluation the effect of tecar therapy in the treatment of frozen shoulder

Design
In this randomized, blinded clinical trial study, 30 patients diagnosed with adhesive capsulitis referred to Baqhai Pour polyclinic will be randomly included in the study. The method of random allocation with block randomization will be used.

Settings and conduct
At first, the patients with adhesive capsulitis in both groups were evaluated in terms of the studied variables before the start of the intervention and underwent the intervention for 6 weeks. Patients were also evaluated in the third and sixth weeks. The statistical analyzer will not know about the grouping of patients.

Participants/Inclusion and exclusion criteria
Patients with shoulder pain for at least one month and limited passive range of motion in comparison to the contralateral shoulder, diagnosed with adhesive capsulitis by a specialist and willing to participate in the study, are enrolled. Patients with a history of diabetes, hypertension, malignancy, fracture, cyst, or lesion in the shoulder area, contraindications for modalities (phototherapy) in patients with bilateral shoulder involvement, shoulder arthritis, calcific tendinitis, significant trauma history, previous shoulder surgery, infection, rheumatoid arthritis, radiculopathy, or reflex sympathetic dystrophy, and unwillingness to continue treatment are excluded from the study.

Intervention groups
The first group was treated for 6 weeks with 3 sessions of thekarotherapy together with oral NSAID treatment and topical ointment, in the second group (control) only received oral NSAID treatment and topical ointment under the supervision of a physical therapist.

Main outcome variables
Pain intensity and shoulder pain and disability index (SPADI), calculation of range of motion, age and gender and duration of the disease will be recorded by a checklist designed for this purpose.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230523058272N1**
Registration date: **2023-06-03, 1402/03/13**
Registration timing: **prospective**

Last update: **2023-06-03, 1402/03/13**
Update count: **0**

Registration date
2023-06-03, 1402/03/13

Registrant information
Name
atefe Rezayan Abarghoi
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-07-21, 1402/04/30
Expected recruitment end date
2023-08-21, 1402/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of thecarotherapy on the range of motion in patients with frozen shoulder

Public title
The effect of thecarotherapy on the range of motion in patients with frozen shoulder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients diagnosed with adhesive capsulitis by a physical medicine specialist who are in the first or second phase of frozen shoulder.

Exclusion criteria:
With a history of diabetes, blood pressure, malignancy and fractures A cyst or lesion in the shoulder area Contraindications for performing modalities (photoallergy) for patients with bilateral shoulder involvement Shoulder arthritis Calcific tendonitis History of significant trauma Previous shoulder surgery infection Rheumatoid Arthritis Radiculopathy and/or sympathetic reflex dystrophy

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this clinical trial study, 30 patients with the diagnosis of adhesive capsulitis, referring to Bekayi Por polyclinic, will be randomly included in the study. Block randomization will be used to randomly assign people in the study groups (intervention group and comparison group). In this method, blocks of 6 (including three people in the intervention group and three people in the comparison group) will be used with a ratio of 1:1. Random Allocation software will be used to generate random sequences. For concealment, the random allocation concealment method will be used in such a way that the random sequences created in this method are recorded on cards and these cards will be placed in sealed envelopes in order. In order to maintain the created sequence, numbering will be done on the outer surface of the envelopes. Finally, the numbered envelopes will be placed in a folder. Then, based on the order of arrival of the eligible participants, the envelopes will be opened and the assigned group of that participant will be known.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, according to the way the treatment process is performed under the supervision of the researcher and is performed for the patients using the Tekar therapy device, the patients and the researcher were aware of the grouping. Of course, at the end of the design, before the data analysis by the analyzer, the names of the groups are changed to groups A and B so that the analyzer does not know about the grouping of patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Sadoughi University of Medical Sciences, Yazd

Street address
Department of Physical Medicine, Shahid Sadoughi Hospital, ebne Sina Boulevard, Yazd, Iran.

City
yazd

Province
Yazd

Postal code
8915887857

Approval date
2022-11-16, 1401/08/25

Ethics committee reference number
IR.SSU.MEDICINE.REC.1402.072

Health conditions studied

1

Description of health condition studied
Adhesive capsulitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
vas

Timepoint
At the beginning of the study, the third and sixth weeks

Method of measurement
Using a ten-point scale to measure pain

2

Description
spadi
Timepoint
At the beginning of the study, the third and sixth weeks
Method of measurement
questionnaire

3

Description
ROM
Timepoint
At the beginning of the study, the third and sixth weeks
Method of measurement
Examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For 6 weeks, three sessions per week will be treated with tecarotherapy along with oral NSAID treatment and topical ointment.
Category
Treatment - Devices

2

Description
Control group: In the control group, they will only be treated with oral NSAID and topical ointment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baghaipur Polyclinic, Yazd
Full name of responsible person
Atefeh Rezaian abarquei
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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
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Atefeh Rezaian abarquei
Position
Student specializing in physical medicine
Latest degree
Medical doctor
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

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

Only a part of the data, such as the information related to the main outcome or the like, can be shared

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data will be available only to researchers working in academic and scientific institutions

From where data/document is obtainable

Atefeh Rezaian abarquei, dr.arezoorezayan@gmail.com

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

Only the data related to the main results of the study can be presented to the mentioned people after mentioning the valid reason.

Comments