Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The comparison of single session ultrasound-guided corticosteroid injection and radial shock wave therapy in non-calcified shoulder tendinopathy.

Protocol summary

Study aim

The aim of this study is to evaluate the effect of radial shock wave therapy in non-calcified shoulder tendinopathy compared with corticosteroid injection.

Design

The study is a clinical trial single-blinded (analyzers and assessor) study and the sampling is with a simple randomization method. The study population is 36 patients.

Settings and conduct

Patients will be randomly divided into two groups of eighteen.The research was carried out in physical medicine and rehabilitation clinic at Firoozgar hospital.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: - Shoulder tendinopathy as a positive result of specific tests like Neer & Hawkins test. - Visual analog scale above 4 (VAS>4). - The willingness of the patients to participate in the research projects. - Not having shoulder injection in the last 4 months. - Age between 18 and 65 years. - Not being pregnant or having the decision to become pregnant. - The absence of intraarticular injection contraindications such as coagulation disorders or taking anticoagulant medicine. - Having pain for more than 3 months. Exclusion criteria: - Having any kind of mental illness. - Previous history of rotator cuff tear, diabetes, coagulation disorders, fractures, rheumatologic diseases, tumors, and infection.

Intervention groups

Control group:1 cc equal 40 mg triamcinolone with 2 cc of lidocaine using 22 gauge needle under ultrasound guidance (lateral approach) will be injected in the subacromial space. The intervention group will receive three sessions of radial shock wave with Storz device in three consecutive weeks with 2000 pulses of energy and 4 Hz frequency.

Main outcome variables

Pain by Visual Analog Scale and functional ability using Quick DASH questionnaire will be measured before the treatment, two weeks after the treatment and three months later.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181122041727N1**
Registration date: **2019-12-02, 1398/09/11**
Registration timing: **prospective**

Last update: **2019-12-02, 1398/09/11**
Update count: **0**

Registration date

2019-12-02, 1398/09/11

Registrant information

Name

Negar Aflakian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1229

Email address

aflakian.n@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-11, 1398/09/20

Expected recruitment end date

2020-02-09, 1398/11/20

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison of single session ultrasound-guided corticosteroid injection and radial shock wave therapy in non-calcified shoulder tendinopathy.

Public title
The effects of corticosteroid injection and radial shock wave in the shoulder inflammatory disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Shoulder tendinopathy as a positive result of specific tests like Neer & Hawkins test. Visual analog scale above 4 (VAS>4). The willingness of the patients to participate in the research projects. Not having shoulder injection in the last 4 months. Age between 18 and 65 years. Not being pregnant or having the decision to become pregnant. The absence of intraarticular injection contraindications such as coagulation disorders or taking anticoagulant medicine. Having pain for more than 3 months.
Exclusion criteria:
Having any kind of mental illness. Previous history of rotator cuff tear, diabetes, coagulation disorders, fractures, rheumatologic diseases, tumors, and infection.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
simple randomization, in which each member of the community has an equal chance of being independent, is chosen. The randomization method will be used with random and binary blocks. Regarding the sample size of 36 people, 9 quadruple blocks will be generated and numbered using the permutations method. Using the random number table, blocks will be placed together to form a patient allocation sequence to treatment groups. Providers will be unaware of the type of treatment that will be received, as well as the random sequences generated in the length of the study will be unpredictable.
Blinding (investigator's opinion)
Single blinded
Blinding description
1- The outcome assessor, would not be aware of the allocation when assessing the patients in the measuring time points. 2-The data analyzer, would not be aware of the allocation when analyzing.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran Universiy of Medical Science
Street address
Medical faculty, Iran University of Medical Sience, Hemmat High way
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2018-09-23, 1397/07/01
Ethics committee reference number
IR.IUMS.FMD.REC.1397.078

Health conditions studied

1

Description of health condition studied
Shoulder tendinopathy
ICD-10 code
M75.4
ICD-10 code description
Impingement syndrome of shoulder

Primary outcomes

1

Description
The severity of symptoms
Timepoint
Before treatment, two weeks and three months after the end of treatment
Method of measurement
Visual Analog Scale (VAS)

2

Description
The amount of physical performance
Timepoint

Before treatment, two weeks and three months after the end of treatment

Method of measurement

Quick DASH questionnaire (Quick Disabilities of Arm, Shoulder & Hand)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: 1 cc equal 40 mg triamcinolone(Exir Pharmaceutical Company, made in Iran) with 2 cc of 2% lidocaine(Caspian Tamin Pharmaceutical Company, made in Iran) using 22 gauge needle under ultrasound guidance (lateral approach) will be injected in the subacromial space as conventional treatment.

Category

Treatment - Other

2

Description

The intervention group will receive three sessions of radial shock wave in three consecutive weeks with 2000 pulses of energy and 4 Hz frequency. Shock wave device, Storz Medical company, Swiss-made will be used.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Educational Hospital

Full name of responsible person

Dr. Arash Babaei

Street address

Physical medicine and Rehabilitation Department, Firouzgar Hospital, Behafarin St, Karim Khane Zand St, Tehran

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babaei-ghazani.a@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Abas Motovalian

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5th floor, Headquarters, Iran University of Medical Sciences, Hemmat Highway, Tehran

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Negar Aflakian

Position

Resident of Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Physical medicine and Rehabilitation Department, Firouzgar Hospital, Behafarin St, Karim Khane Zand St, Tehran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Dr. Arash Babaei

Position
Associate Professor of Physical Medicine and Rehabilitation

Latest degree
Specialist

Other areas of specialty/work
Physical Medicine

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Person responsible for updating data

Contact

Name of organization / entity
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Position
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Latest degree
Medical doctor

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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