Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

Evaluating the effect of subacromial space injections of Low Molecular Weight Hyaluronic Acid or High Molecular Weight Hyaluronic Acid in comparison with Physiotherapy in Shoulder Tendinopathy. A Three Arm Randomized Controlled Trial.

Protocol summary

Study aim
Evaluating the effect of subacromial space injections of low molecular weight hyaluronic acid or high molecular weight hyaluronic acid in comparison with physiotherapy in shoulder tendinopathy.

Design
Single center, randomized, blinded, phase III clinical trial with a parallel group design of 84 participants with shoulder tendinopathy, equally divided in to three groups, low MW hyaluronic acid, high MW hyaluronic acid and Physiotherapy.

Settings and conduct
Follow-up assessors, statistical data analyzers, and quality controllers are blinded. The injectors and physiotherapist have been excluded from the study and the interventions performed based on the codes provided in a sealed packages.

Participants/Inclusion and exclusion criteria
Participants will be adult patients (16-70 years old) with Shoulder Tendinopathies, with onset of shoulder pain for least 6 weeks . Pediatrics, geriatrics, pregnant, lactating, patient with active rheumatologic disorders, patient with coagulopathies, active infections in shoulder and tissues of around the shoulder, complete rupture of rotator cuff tendons, diabetes mellitus, use of anticoagulant drugs, use of systemic corticosteroid in the last month will be excluded from the study.

Intervention groups
Participants randomly divided in three groups of intervention, first group received low MW hyaluronic acid (Hyalgan®), the second group received high MW hyaluronic acid (Synogel®) and the third group received Physiotherapy.

Main outcome variables
The primary outcome is Visual Analog Scale (VAS). The secondary outcomes will be: 1) the range of motions (ROM) in flexion, extension, abduction, adduction, internal and external rotation, 2) Disability of the Arm Shoulder and Hand (DASH) Questionnaire, 3) Quality Of Life (WHOQOL)-BREF.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170608034390N7**
Registration date: **2021-01-18, 1399/10/29**
Registration timing: **retrospective**

Last update: **2021-01-18, 1399/10/29**
Update count: **0**

Registration date
2021-01-18, 1399/10/29

Registrant information
Name
Hadi Esmaily
Name of organization / entity
SBMU
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-08, 1397/07/16

Expected recruitment end date
2019-09-23, 1398/07/01
Actual recruitment start date
2018-12-07, 1397/09/16
Actual recruitment end date
2020-08-16, 1399/05/26
Trial completion date
2020-12-21, 1399/10/01

Scientific title
Evaluating the effect of subacromial space injections of Low Molecular Weight Hyaluronic Acid or High Molecular Weight Hyaluronic Acid in comparison with Physiotherapy in Shoulder Tendinopathy. A Three Arm Randomized Controlled Trial.

Public title
Comparison between effectiveness of two different molecular weights of hyaluronic acid and physiotherapy on shoulder tendinopathy.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Tendinopathy of shoulder Adults (16-70 years) At least 6 weeks from the onset of pain
Exclusion criteria:
Pregnant or lactating Women Active systemic rheumatologic disorders Coagulopathies or on anticoagulant medication Diabetes mellitus Active septic disorders or history of cancers or tumors around the site of shoulder joint Use of systemic corticosteroid drugs recently in one month
Age
From **16 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **84**
Actual sample size reached: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were divided with the same ratio in three groups and a web base software (www.sealedenvelope.com) was applied and 14 blocks of 6 subjects were created for block randomization.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Researchers including the physician who assess the eligibility of patients, the physician who monitors response to interventions, the statistical analyst, and the controller of study quality, were all blinded, but due to the different nature of interventions, it was not possible to blind the administrants, in this regards a sealed envelope containing the patient's treatment code was sent to injector and physiotherapist who only administered the interventions based on the codes, and they were excluded from the patient eligibility, treatment and outcome assessments. Since one of the interventions was physiotherapy, it was not possible to blind patients.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of
Street address
Central department of ministry of health and medical education, Simaye Iran st, Shahrak Ghods
City
Tehran
Province
Tehran
Postal code
1467664961
Approval date
2018-10-08, 1397/07/16
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1397.130

Health conditions studied

1

Description of health condition studied
shoulder tendinophaty(Rotator cuff tendinopathy)
ICD-10 code
M75.80
ICD-10 code description
Other shoulder lesions, unspecified shoulder

Primary outcomes

1

Description
Pain intensity based on visual analogue scale
Timepoint
Measuring the severity of pain at the beginning of the study (before the intervention), one week, one month

and three months after the injection.

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

Range of Motion (ROM)

Timepoint

Measuring the range of motion at the beginning of the study (before the intervention), one week, one month and three months after the injection.

Method of measurement

Goniometer

2

Description

Pain of the injection site

Timepoint

Check for the pain at the injection site, one day after injection

Method of measurement

Visual Analogue Scale (VAS)

3

Description

The disabilities of the arm, shoulder and hand

Timepoint

Measuring the disabilities of the arm, shoulder and hand at the beginning of the study (before the intervention), one week, one month and three months after the injection.

Method of measurement

The Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire

4

Description

Quality of life

Timepoint

Measuring the Quality of life at the beginning of the study (before the intervention), one week, one month and three months after the injection.

Method of measurement

QOL-BREF Questionnaire

Intervention groups

1

Description

Intervention group: High MW of Hyaluronic acid (Synogel® MW>2000 KD) injection in subacromial space of shoulder with Codman's (pendulum) Exercises

Category

Treatment - Drugs

2

Description

Intervention group: Low MW of Hyaluronic acid (Hyalgan® MW= 500-700 KD) injection in Subacromial space of shoulder with Codman's (pendulum) Exercises

Category

Treatment - Drugs

3

Description

Intervention group: For the Physiotherapy group, it prescribed 3 sessions of treatment per week for 4 weeks, totaling 10 sessions, with Codman's (pendulum) Exercises

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, 501 Army

Full name of responsible person

Zahra Reza Soltani

Street address

Imam Reza Hospital, 501 Army_ Shahid Etemadzadeh St_West Fatemi Ave_Tehran

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z.rezasoltani@ajaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Taleghani Hospital, Shahid Arabi Ave, Yemen Ave, Shahid Chamran Highway

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hadi Esmaily

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Position

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Specialist

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Rezvaneh Mohebbi

Position

Student

Latest degree

Medical doctor

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Potentially the whole data is published after participants become unidentified.

When the data will become available and for how long

The access Starts in 6 months period after publishing of the results.

To whom data/document is available

Researchers working in academic and industrial institutions.

Under which criteria data/document could be used

It can be used to carry out research work.

From where data/document is obtainable

Dr. Hadi Esmaily, Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences.

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

It will be available with sending a request by email to corresponding author (Esmaily_hadi@sbmu.ac.ir).

Comments