

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

A Comparison between subacromial space injections of Low Molecular Weight Hyaluronic Acid (Hyalgan® MW= 500-700 KD) and High Molecular Weight Hyaluronic Acid (Synogel® MW>2000 KD) in Rotator Cuff Tendinopathy.

Protocol summary

Study aim

A comparison between effectiveness of subacromial space injections of low MW hyaluronic acid with high MW in the treatment of rotator cuff tendinopathy.

Design

Single center, randomized, blinded, phase III clinical trial with a parallel group design of 56 participants with rotator cuff tendinopathy equally divided in to two groups, low MW hyaluronic acid (Hyalgan®) and high MW hyaluronic acid (Synogel®).

Settings and conduct

In this study participants, investigators, outcome assessors, data analyst and the quality controller are blinded and only the expert who does the injection could not be blinded because of the difference in the viscosity, and will be excluded from the investigation and follow-ups, he will only do the injection based on the code in sealed envelope provided by the investigator.

Participants/Inclusion and exclusion criteria

Participants will be adult patients (16-70 years old) with Rotator Cuff 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 two groups of intervention, first group received low MW hyaluronic acid (500-700 KD, Hyalgan®), and the second group received high MW hyaluronic acid (>2000 KD, Synogel®).

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: **IRCT20170608034390N5**

Registration date: **2020-01-16, 1398/10/26**

Registration timing: **retrospective**

Last update: **2020-01-16, 1398/10/26**

Update count: **0**

Registration date

2020-01-16, 1398/10/26

Registrant information

Name

Hadi Esmaily

Name of organization / entity

SBMU

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

esmaily_hadi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

2018-09-01, 1397/06/10

Actual recruitment end date

2019-10-07, 1398/07/15

Trial completion date

2020-01-05, 1398/10/15

Scientific title

A Comparison between subacromial space injections of Low Molecular Weight Hyaluronic Acid (Hyalgan® MW= 500-700 KD) and High Molecular Weight Hyaluronic Acid (Synogel® MW>2000 KD) in Rotator Cuff Tendinopathy.

Public title

Comparison between effectiveness of two different molecular weights of hyaluronic acid on shoulder tendinopathy.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Tendinopathy of Rotator Cuff 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

AgeFrom **16 years** old to **70 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample sizeTarget sample size: **56**Actual sample size reached: **56****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients were divided with the same ratio in two groups and a web base software (www.sealedenvelope.com) was applied and 14 blocks of 4 subjects were created for block randomization.

Blinding (investigator's opinion)

Triple blinded

Blinding description

All Participants, Investigators, Outcome assessors, Data analyst and quality controller are blinded. Sequentially numbered opaque sealed envelopes containing treatment allocations were prepared and were opened in

sequence by an independent administrator who was not involved in eligibility, treatment, or outcome measurement.

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

2018-05-28, 1397/03/07

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1397.039

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

Rotator cuff tendinopathy

ICD-10 code

M75.102

ICD-10 code description

Unsp rotatr-cuff tear/ruptr of left shoulder, not trauma.

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

Adverse events (e.g., Inflammation in the injection site)

Timepoint

Inflammation in the injection site at the first week of study after the injection.

Method of measurement

Hyperemia, warmth, pain, tendonitis, tenderness

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

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 Etemadzade St_ West Fatemi Ave_ Tehran

City

Tehran

Province

Tehran

Postal code

88028724

Phone

+98 21 4382 3476

Email

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

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9780

Email

zarghi@sbmu.ac.ir

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

Street address

Shahid Beheshti Pharmaceutical Faculty, Vali Asr Ave.

City

Tehran

Province

Tehran

Postal code

1991953381

Phone

+98 21 8820 0118

Email

Esmaily_hadi@sbm.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hadi Esmaily

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Shahid Beheshti Pharmaceutical Faculty, Vali Asr Ave.

City

Tehran

Province

Tehran

Postal code

1991953381

Phone

+98 21 8820 0118

Fax

Email

Esmaily_hadi@sbm.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rezvaneh Mohebbi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Shahid Beheshti Pharmaceutical Faculty, Vali Asr Ave

City

Tehran

Province

Tehran

Postal code

1991953381

Phone

+98 21 8820 0118

Email

rzvnmhbbi@gmail.com

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 request.

Comments