

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A Comparison between Low Molecular Weight Hyaluronic Acid (Hyalgan® MW= 500-700 KD) and physiotherapy in supraspinatous Tendinopathy.

Protocol summary

Study aim

The aim of this study is evaluating the comparative efficacy and safety of intraarticular space injections of low MW hyaluronic acid and physiotherapy in the shoulder Tendinopathy.

Design

Two parallel group with randomization performed by computer. not blinded and consists of 56 patients.

Settings and conduct

This study is a randomized, multifaceted, not blind clinical trial. The study was performed at Imam Reza Hospital and patients were referred to the hospital again.

Participants/Inclusion and exclusion criteria

Admission: Adults with shoulder tendonitis who are under 65 years of age. Patients with shoulder tendonitis who have had at least 6 weeks and a maximum of three months since the onset of the disease. Lack of entry conditions: Patients with complete tendon rupture diagnosed with MRI. They had a corticosteroid injection less than 3 months ago. Patients with rheumatoid arthritis, multiple sclerosis, ankylosing spondylitis, chemotherapy, fractures and radicular pain in the neck and pregnant women.

Intervention groups

If patients were not barred from injecting hyaluronic acid, they were divided using a table of codes and received one group of intramuscular injections of low molecular weight hyaluronic acid (500-700 kDa) and the other group received physical therapy.

Main outcome variables

Visual Analogue Scale (VAS Score) in three night modes, during activity and rest, Range of Motion (ROM) including Flexion, Extension, Adduction, Abduction, Internal Rotation and External Rotation, Hand Disability Questionnaire, Arm And the shoulder (DASH) and the QoL-bref quality of life questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150118020702N3**

Registration date: **2020-06-22, 1399/04/02**

Registration timing: **retrospective**

Last update: **2020-06-22, 1399/04/02**

Update count: **0**

Registration date

2020-06-22, 1399/04/02

Registrant information

Name

mansoureh rousta

Name of organization / entity

tehran university of medical science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

2018-07-23, 1397/05/01

Actual recruitment end date

2020-02-20, 1398/12/01

Trial completion date

2020-02-20, 1398/12/01

Scientific title

A Comparison between Low Molecular Weight Hyaluronic Acid (Hyalgan® MW= 500-700 KD) and physiotherapy in supraspinatous Tendinopathy.

Public title

Evaluation of Low Molecular Weight Hyaluronic Acid in treatment of supraspinatous Tendinopathy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult less than 65 years old with supraspinatous tendinitis Patient with supraspinatous tendinitis who's that between lowermost 6 weeks and uppermost 3 month from initial symptom.

Exclusion criteria:

Patient with complete tendon tearing in MRI study
Patient had corticosteroid injection less than 3 month ago. Patient with RA, MS, AS, OP, FX, radicular pain of neck and pregnant women.

Age

To **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **51**

Actual sample size reached: **51**

Randomization (investigator's opinion)

Randomized

Randomization description

For the random allocation of participants to two groups with the same size of 28 participants (56 patients in total), we used block randomization. Random numbers were generated in an independent statistical room and with the help of a computer.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Army university of medical sciences

Street address

Etemadzadeh St., Army University of Medical Sciences, School of Medicine

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Approval date

2020-02-16, 1398/11/27

Ethics committee reference number

IR.AJAUMS.REC.1398.253

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

Supraspinatous thendinopathy

ICD-10 code

M75.10

ICD-10 code description

Unspecified rotator cuff tear or rupture, not specified as traumatic

Primary outcomes**1****Description**

Visual Analogue Scale (VAS Score)

Timepoint

Immediately after the injection, one week, one month, and three months after the injection.

Method of measurement

The patient answer the question of VAS score questionnaire in 3 modes of rest,activity,and night 3 times after 1week,after1 month and after 3 months of procesure

2**Description**

DASH

Timepoint

Immediately after the injection, one week, one month, and three months after the injection.

Method of measurement

The patient answer the question of DASH questionnaire in 3 times after 1week,after1 month and after 3 months of procesure

3**Description**

Quality of life

Timepoint

Immediately after the injection, one week, one month, and three months after the injection.

Method of measurement

The patient answer the questionnaire 3 times after 1week,after1 month and after 3 months of procesure.

4

Description

Range of motion(flexion,extention,medial rotation,lateral rotation,abduction,adduction)

Timepoint

Immediately after the injection, one week, one month, and three months after the injection.

Method of measurement

Rom of shoulder of patient in each motion measured by goniometer in 1 week,1 month and 3 month after procedure.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: hyaluronic acid injection performed by physiatrist in tendon.each 2 ml syringe contains hyaluronic acid 20mg. One injection performed with sterility.This drug produced in italy.After injection plected ice in the site of injection and care rules told to patient.

Category

Treatment - Drugs

2

Description

Intervention group2: in this group patient underwent physiotherapy.physiotherapy contains US,TENS and exercise.10 set of physiotherapy performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital 501

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

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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

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Mansoure Rousta

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not 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

No - There is not 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