

# 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)

##### Phone

+98 21 8691 5234

##### Email address

m.rousta1991@gmail.com

##### 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1411718541

##### 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**

Mansoure Rousta

##### **Street address**

Etemadzade

##### **City**

Tehran

##### **Province**

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##### **Postal code**

1411718541

##### **Phone**

+98 21 8609 6350

##### **Email**

m.rousta1991@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Artesh University of Medical Sciences

##### **Full name of responsible person**

Reza soltani Zahra

##### **Street address**

Etemadzade

##### **City**

Tehran

##### **Province**

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##### **Postal code**

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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**

Physical Medicine

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Latest degree**

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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