

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Evaluating the Efficacy and Safety of adding Intra- Articular High Molecular Weight Hyaluronic Acid (Viscor® MW>2000 KD) Injections in Comparison of Low Molecular Weight Hyaluronic Acid (Hyalgan® MW= 500-800 KD) and lidocaine In Idiopathic Adhesive Capsulitis

Protocol summary

Study aim

The aim of this study is to investigate the add on effectiveness and safety of intra-articular injection of two types of hyaluronic acid differ on the molecular weight and with physical therapy of adult patients with adhesive capsulitis.

Design

A randomized, blinded and parallel group trial. Randomization was done with block randomization method, with 50 patient equally enrolled in 2 parallel groups.

Settings and conduct

The recruitment of patients will be done in Shahid Modarres Hospital, Tehran, Iran. All Participants, Investigators, Outcome assessors, Data analyst and quality controller are blinded

Participants/Inclusion and exclusion criteria

Adult Patients (16-65 years) who were diagnosed as adhesive capsulitis in the last month were included in this study, whom who had a history of traumatic injury to shoulder, active tendonitis and history of rotator cuff tears were and who have used systemic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) in last week and systemic corticosteroids in last month were excluded from this study.

Intervention groups

One group received intra-articular injection of high molecular weight hyaluronic acid (Viscor® >2000 KD) and second group revived intra-articular injection of low molecular weight hyaluronic acid (Hyalgan® 500-800 KD), physical therapy will be learned to both groups.

Main outcome variables

The primary outcome is visual analog score difference, The secondary outcomes will be active, passive, internal, external range of motion, oxford score and patient satisfaction.

General information

Reason for update

The results of the study at the end of the 12-week follow-up period showed that the two groups did not have a significant difference in terms of study outcomes, considering that the duration of effect of the injections of two molecular weights of hyaluronic acid could have been different in a longer period, the research team of the study was decided to continue the study for 24 weeks follow-up, due to the lack of complete referral of the patients included in the study in the 24-week follow-up, patient recruitment was continued again until the study reached the desired sample size.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170608034390N4**
Registration date: **2020-01-01, 1398/10/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-03, 1401/07/11**

Update count: **1**

Registration date

2020-01-01, 1398/10/11

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**

2018-11-22, 1397/09/01

Expected recruitment end date

2022-03-01, 1400/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Efficacy and Safety of adding Intra-Articular High Molecular Weight Hyaluronic Acid (Viscor® MW>2000 KD) Injections in Comparison of Low Molecular Weight Hyaluronic Acid (Hyalgan® MW= 500-800 KD) and lidocaine In Idiopathic Adhesive Capsulitis

Public title

Comparing the Add on Effectiveness of Intra-Articular Injections of High Molecular Weight Hyaluronic Acid (Viscor®>2000 KD) with Low Molecular Weight Hyaluronic Acid (Hyalgan® MW= 500-800 KD) and Lidocaine In Frozen Shoulder Conventional Physical Therapy.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adults (>18 years) Less than 65 years old It takes less than three month from the onset of the disorder

Exclusion criteria:

History of Traumatic Injury to the shoulder Active Tendonitis History of rotator cuff tear History of NSAIDs use during the last week History of systemic corticosteroid use during the last 1 month

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

We used block randomization method.

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**

National Ethics Committee for Biomedical Research

Street address

Central Department of Ministerial of Health and Medical Education, Sima Iran St, between South Falamak and Zarafshan St, Shark Gharb

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2018-11-13, 1397/08/22

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1397.084

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

Idiopathic Adhesive Capsulitis (Frozen Shoulder)

ICD-10 code

M75.00

ICD-10 code description

Adhesive capsulitis of unspecified shoulder

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

Pain

Timepoint

At baseline, 4, 12 and 24 weeks after injection

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Range of Motion

Timepoint

At baseline, 4 and 12 weeks after injection

Method of measurement

Goniometry

2

Description

Inflammation Signs and Symptoms

Timepoint

at baseline of injection

Method of measurement

Hyperemia, Warmly, Pain, Tendonitis, Tenderness

3

Description

Oxford Shoulder Score

Timepoint

At baseline, 4 and 12 weeks after injection

Method of measurement

Oxford Questionnaire

Intervention groups

1

Description

Intervention group: One arm revied intra-articular injection of High Molecular Weight hyaluronic acid (Viscor® >2000 KD) in shoulder joint adding to the conventional physical therapy.

Category

Treatment - Drugs

2

Description

Intervention group: Second arm revied intra articular injection of Low Molecular Weight hyaluronic acid (Hyalgan® 500-800 KD) in shoulder joint adding to the conventional physical therapy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

Seyed Ahmad Raeis Sadat

Street address

Saadat Abad St. Tehran

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Tehran

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1998734383

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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 st, yemen ave, shahid chairman highway

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1985717443

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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

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1991953381

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Esmaily_hadi@sbmu.ac.ir

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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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 Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahshad Mir

Position**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

the whole potential data is unpublished after being unidentifiable.

When the data will become available and for how long

start the access period 6 month after pricing the result

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 science

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

sending request is available.

Comments