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)

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+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 revived 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 revived 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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Email
a_raeissadat@sbmu.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 st, yemen ave, shahid chairman highway
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1985717443
Phone
+98 21 2243 9780
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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
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Person responsible for updating data

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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
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