

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Effect of eight weeks of rehabilitation exercises on rotator cuff's architecture and function after remplissage procedure on hill-sachs defect

Protocol summary

Study aim

The effect of eight weeks of rehabilitation exercises on rotator cuff's architecture and function after remplissage procedure on hill-sachs defect

Design

reviewing the records and evaluation of patients with Hill-Sachs injury and entering the subjects in the rehabilitation training program. The simple non-random form will be divided into experimental and control groups.

Settings and conduct

After surgery, the condition of the muscle architecture is determined. Functional evaluations (strength, proprioception and range of motion) will be performed and training interventions will be performed. Pre-tests and post-tests include the evaluation of muscle structural changes by the ultrasound device and the range of motion by the Mobi Mod device, proprioception and strength. It will be measured by the Biodex system.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of the patients should be between 23 to 33 years old. Body mass index (BMI) should be less than 25. No previous history of shoulder surgery. Exclusion criteria before randomization: Must not have musculoskeletal and metabolic diseases, inability to perform pre-test sections

Intervention groups

patients will first undergo shoulder remplissage surgery and then the samples of this study, which will be randomly divided into Experimental groups and control group. The groups will be evaluated to measure the amount of strength, range of motion and proprioception. Then the intervention, specific training program, will be performed to determine the effectiveness of the exercises for eight weeks.

Main outcome variables

Muscle architecture, isokinetic strength, range of motion,

proprioception

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220420054598N1**

Registration date: **2022-10-21, 1401/07/29**

Registration timing: **prospective**

Last update: **2022-10-21, 1401/07/29**

Update count: **0**

Registration date

2022-10-21, 1401/07/29

Registrant information

Name

Sam Shajarian

Name of organization / entity

Shahid Beheshti University

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 3413

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of eight weeks of rehabilitation exercises on rotator cuff's architecture and function after remplissage procedure on hill-sachs defect

Public title
Effect of eight weeks of rehabilitation exercises on rotator cuff's architecture and function after remplissage procedure on hill-sachs defect

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age of the patients should be between 23 to 33 years old
 Body mass index (BMI) should be less than 25 No previous history of shoulder surgery
Exclusion criteria:
 Must not have musculoskeletal and metabolic diseases
 Inability to perform pre-test sections

Age
From **23 years** old to **33 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization, In this method, we should use simple randomization models such as tap or line, using a table of random numbers, or using computer randomization methods, and assign each client to the intervention group, for example, by tossing a coin, tapping and drawing a line, or We control.

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 Shahid beheshti University

Street address

Ethics committee, Shahid Beheshti University, Shahid Dr. Shahriari Square (University Square), Rashiduddin Fazlullah St., Yaman St., Velanjak, Chamran Highway, Tehran

City

Tehran

Province

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Postal code

19839694111

Approval date

2022-04-30, 1401/02/10

Ethics committee reference number

IR.SBU.REC.1401.014

Health conditions studied

1

Description of health condition studied

hill Sachs lesion

ICD-10 code

S43

ICD-10 code description

Dislocation and sprain of joints and ligaments of shoulder girdle

Primary outcomes

1

Description

Muscle architecture changes

Timepoint

eight weeks

Method of measurement

Ultrasonography & MRI

2

Description

Range of motion

Timepoint

eight weeks

Method of measurement

Mobee Med (for measuring range of motion)

3

Description

Strength

Timepoint

eight weeks

Method of measurement

Biodex System model pro 4 (for measuring strength)

4

Description

Proprioception

Timepoint

eight weeks
Method of measurement
Biodex System model pro 4 (for measuring proprioception)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the experimental group, after reviewing the records and evaluation of patients with Hill-Sachs injuries, 15 patients will be selected by the surgeon to implement the post-operative rehabilitation exercise program, and then by obtaining written informed consent and registering the data collection form of the subjects. including age, sports history, etc., these people will be invited to do the pre-test (measurement of muscle architecture factors, strength, range of motion, and proprioception) and follow the exercise program (for 8 week) and finally the post-test (measurement of muscle architecture factors, strength, range of motion, and proprioception) will be taken.

Category

Rehabilitation

2

Description

Control group: The control group, after examining the records and evaluating the patients with heel-sachs injury, 15 patients by obtaining written informed consent and registering the form to collect the subjects' information, including age, sports history, etc., by surgeon, from These people will be invited to participate in this research. At first, the people did the pre-test (measurement of muscle architecture factors, strength, range of motion, and proprioception) and in these 8 weeks, they just continued with their routine activities. and finally, after 8 weeks, the post-test (measurement of muscle architecture factors, strength, range of motion, and proprioception) will be taken.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar Hospital

Full name of responsible person

Hamidreza Aslani

Street address

Akhtar Orthopedic Center, Azar Dead End, Sharifi Menesh St., Romi Pol, Shariati St., Tehran

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1964714953
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+98 21 2200 1072
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akhtarhospital@gmail.com
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University

Full name of responsible person

□Fariborz Hovanloo

Street address

School of Sports and Health Sciences, Shahid Beheshti University, Shahid Dr. Shahriari Square (University Square), Rashiduddin Fazlullah St., Yaman St., Velanjak, Chamran Highway, Tehran

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sportscience@sbu.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

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

Shahid Beheshti University

Full name of responsible person

Fariborz Hovanloo

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physical Education

Street address

School of Sports and Health Sciences, Shahid Beheshti University, Shahid Dr. Shahriari Square (University Square), Rashiduddin Fazlullah St., Yaman St., Velanjak, Chamran Highway, Tehran

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Shahid Beheshti University

Full name of responsible person

Fariborz Hovanloo

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Fariborz Hovanloo

Position

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Latest degree

Ph.D.

Other areas of specialty/work

Physical Education

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

The information about the subjects is personal and will not be shared with others.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All information except the subjects' personal information.

When the data will become available and for how long

Six months after the results are published.

To whom data/document is available

All researchers.

Under which criteria data/document could be used

The use of research results is unimpeded by acquiring the source.

From where data/document is obtainable

email:s.shajarian@mail.sbu.ac.ir

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

At least two working days.

Comments