

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Investigation of the effect of limb immobilization in external rotation on recurrent anterior shoulder dislocation in patients admitted to hospitals of Mashhad University of Medical Sciences

Protocol summary

Study aim

The effect of limb immobilization in external rotation on recurrent anterior shoulder dislocation

Design

In this study, all patients with anterior shoulder dislocation referring to Imam Reza, Shahid Kamiab and Hasheminejad hospitals enter the study after obtaining informed consent. Using random numbers and envelope method, Patients will be divided into intervention and control groups.

Settings and conduct

In the intervention group, immobilization is performed as an external rotation and in the control group, immobilization is performed as an internal rotation (commonly used method) for 4 weeks. The range of shoulder movement questionnaire is completed for each patient immediately after removal of the brace, 3 months, one year and two years after the immobilization, the Oxford questionnaire is completed 3 months, one year and 2 years after the immobilization. Patients are followed up for dislocation recurrence within two years. Patients' comfort in each brace is assessed through a questionnaire.

Participants/Inclusion and exclusion criteria

inclusion criteria: Shoulder dislocation Exclusion criteria: A history of shoulder dislocation, Fracture of the scapular and humerus, History of underlying diseases affecting study outcomes such as osteoporosis and inflammatory and autoimmune diseases.

Intervention groups

Intervention group: After the shoulder is placed back in position, the immobilization is in a rotational state outward and at a distance from the axis of the body, and armpit cushion is used for the injuerd. Control group: After the shoulder is placed back in position, the immobilization is routine and is rotated indoors and spaced apart from the axis of the body.

Main outcome variables

recurrent anterior shoulder dislocation, shoulder range of motion; the quality of patient's life; patients' comfort in brace

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171205037766N1**

Registration date: **2018-08-01, 1397/05/10**

Registration timing: **retrospective**

Last update: **2018-08-01, 1397/05/10**

Update count: **0**

Registration date

2018-08-01, 1397/05/10

Registrant information

Name

Mohamadkazem Khalesi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3858 1344

Email address

khalesimk921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

2014-08-23, 1393/06/01
Actual recruitment end date
2016-06-19, 1395/03/30
Trial completion date
empty
Scientific title
Investigation of the effect of limb immobilization in external rotation on recurrent anterior shoulder dislocation in patients admitted to hospitals of Mashhad University of Medical Sciences

Public title
The effect of limb immobilization in external rotation in anterior shoulder dislocation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Anterior shoulder dislocation

Exclusion criteria:

A history of shoulder dislocation Fracture of the scapular and humerus History of underlying diseases affecting study outcomes such as osteoporosis and inflammatory and autoimmune diseases

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **200**
Actual sample size reached: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization is applied. Selective treatment is placed in sealed envelopes. Type of treatment is determined by random selection of envelopes.

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 Mashhad University of Medical

Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
345 - 91357

Approval date
2012-06-23, 1391/04/03

Ethics committee reference number
IR.MUMS.REC.1391.94

Health conditions studied

1

Description of health condition studied
Shoulder dislocation

ICD-10 code
S43.0

ICD-10 code description
Subluxation and dislocation of shoulder joint

Primary outcomes

1

Description
recurrent anterior shoulder dislocation

Timepoint
Following up with patients is carried out for at least 2 years.

Method of measurement
Physical examination

2

Description
Shoulder range Of motion

Timepoint
For each patient, immediately after removing the brace, 3 months, one year, and 2 years after immobilization.

Method of measurement
Range Of Motion Shoulder (ROM) questionnaire completed by the researcher.

3

Description
Quality of life in patients with shoulder problems

Timepoint
Three months, one year and two years after immobilization.

Method of measurement
Oxford Shoulder questionnaire

4

Description

Evaluation of patients' comfort in brace

Timepoint

After the end of treatment

Method of measurement

Visual Analog Scale (VAS) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the shoulder is placed back in position, the immobilization is in a rotational state outward and at a distance from the axis of the body and an armpit cushion is placed for the injured.

Category

Treatment - Devices

2

Description

Control group: After the shoulder is placed back in position, the immobilization is routine and is rotated indoors and spaced apart from the axis of the body.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Mohammad Kazem Khalesi

Street address

Emam Reza hospital, Emam Reza Sq, Ebne-Sina Ave

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9137913316

Email

KhalesiMK921@mums.ac.ir

2

Recruitment center

Name of recruitment center

Shahid Hashemi Nezhad Hospital

Full name of responsible person

Mohammad Kazem Khalesi

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3

Recruitment center

Name of recruitment center

Shahid Kamyab Hospital

Full name of responsible person

Mohammad Kazem Khalesi

Street address

Shahid Kamyab Hospital, Nakhrisi junction, Fadaeian Eslam St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mohammad Kazem Khalesi
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available