Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

City

Mashhad

Province

Razavi Khorasan

Postal code

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

Street address

Shahid Hashemi Nezhad Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3273 7015

Email

KhalesiMK921@mums.ac.ir

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.

City

Mashhad

Province

Razavi Khorasan

Postal code

9166637477

Phone

+98 51 3802 6351

Email

KhalesiMK921@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

345 - 91357

Phone

+98 51 3841 2081

Email

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

Street address

Ghaem hospital, Ahmad Abad Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3801 2610

Email

khalesimk921@mums.ac.ir

Person responsible for scientific 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

Street address

Ghaem hospital, Ahmad Abad Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3801 2610

Email

khalesimk921@mums.ac.ir

Person responsible for updating data

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

Street address

Ghaem hospital, Ahmad Abad Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3801 2610

Email

khalesimk921@mums.ac.ir

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