

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of Upper Limb Function with Sling and Abduction Pillows after Proximal Humerus Tow-Part Fracture Surgery

Protocol summary

Study aim

Comparison of Upper Limb Function with Sling and Abduction Pillows after Proximal Humerus Tow-Part Fracture Surgery

Design

In this double-blind clinical trial study (participants and results analyzer), patients will undergo surgery after random allocation in the two mentioned groups. Slings will be used for one group and Abduction Pillows for the other group for 6 weeks after surgery.

Settings and conduct

This study is a randomized clinical trial (blocks of four), double-blind (participants and results analyzer), with parallel groups, without a control group and , with the participation of 80 patients with Tow-Part fractures of the proximal humerus. It will be done at Imam Reza Hospital (Tabriz).

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Tow-Part proximal humerus fracture and surgery performed by a single surgeon, and exclusion criteria also include: patients with a history of previous surgery in the shoulder or elbow joint area on the same side, patients with osteoporosis and patients with nerve damage in the shoulder area.

Intervention groups

In this study, patients who undergo surgery due to tow-part fractures of the proximal humerus will be included in the study. Patients will be randomly divided into two groups. Slings will be used for one group and Abduction Pillows for the other group for 6 weeks after surgery. The status of upper limb function will be measured and compared between the two groups with the help of the DASH instrument in the sixth week after surgery.

Main outcome variables

Upper limb function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N37**

Registration date: **2023-11-13, 1402/08/22**

Registration timing: **prospective**

Last update: **2023-11-13, 1402/08/22**

Update count: **0**

Registration date

2023-11-13, 1402/08/22

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-05, 1402/09/14

Expected recruitment end date

2024-03-04, 1402/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Upper Limb Function with Sling and Abduction Pillows after Proximal Humerus Tow-Part Fracture Surgery

Public title

Comparison of Upper Limb Function with Sling and Abduction Pillows

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Tow-part proximal humerus fracture Surgery performed by a single surgeon

Exclusion criteria:

Patients with a history of previous surgery in the area of the shoulder or elbow joint on the same side Patients with osteoporosis Patients with shoulder nerve injuries

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, with a sample size of 80, we use the patients using the block permutation randomization method, which is used in this method to balance the number of allocated samples, and with 4 people in each block. We assemble the possible blocks as follows. block 1: BBAA, block 2: AABB, block 3: ABAB, block 4: BABA, block 5: ABBA, and block 6: BAAB, we need 20 blocks for 80 people. It is random in the block method. We choose numbers from one to six. For example, if number 6 is chosen as the first block and number 2 as the second block, the people who enter the study will be given BAABAABB in order from left to right. and finally they were divided into two intervention groups (group A) and control group (group B).

Blinding (investigator's opinion)

Double blinded

Blinding description

The thesis results analyst who will analyze the expected result and also the participants will be unaware of the type of procedure performed and will be blind during the study; Therefore, this study will be conducted in a double-blind manner. Since the participants will be unaware of the type of equipment used, in this study they will not know what type of equipment will be used in other patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2022-10-02, 1401/07/10

Ethics committee reference number

IR.TBZMED.REC.1401.581

Health conditions studied

1

Description of health condition studied

Upper limb function

ICD-10 code

H81.8X

ICD-10 code description

Other disorders of vestibular function

Primary outcomes

1

Description

Upper limb function

Timepoint

Six weeks after surgery and only once

Method of measurement

DASH (Disabilities of arm, shoulder & hand) score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After surgery, the patients of this group will be treated with a simple sling, and the duration of using the sling will be 6 weeks. All patients will visit the relevant doctor in the sixth week after surgery for examination and evaluation based on the DASH instrument.

Category

Treatment - Devices

2**Description**

Control group: The patients of this group will be subjected to intervention in the form of abduction pillows after the surgery, and the duration of using the sling will be 6 weeks. All patients will visit the relevant doctor in the sixth week after surgery for examination and evaluation based on the DASH instrument.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Sina Ghasemi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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