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

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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

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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
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Associate professor
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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