Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of treatment of Volar Barton fracture with T plate using distal end screws and without distal end screws

Protocol summary

Study aim
To compare treatment of volar Barton's fracture with T plate using distal end screws and without using distal end screws in terms of pain, range of motion (ROM), grip strength and activities compared to opposite side.

Design
An open labelled, randomized controlled trial with parallel group designed of 60 patients, enrolling between March 2023 to December 2023.

Settings and conduct
This open label randomized controlled trial be conducted at the Department of Orthopedics unit-2 Mayo Hospital Lahore, Pakistan

Participants/Inclusion and exclusion criteria
Inclusion criteria were patients of either gender aged 18-60 years with closed volar Barton's fracture with Mehara classification types-1 & II of duration < 5 days. Exclusion criteria were patients with infections, extensive comminution, open fracture with extensive soft tissue damage or contamination, neurological deficit, head injury or major vascular injury, ipsilateral upper limb trauma or those non-compliant to postoperative physiotherapy and follow up. Patients with severe osteoporosis or those with reduced functional requirement of wrist were also excluded.

Intervention groups
In Group-A, patients were used T-plate with distal end screws and in Group-B, patients were used T-plate without distal end screws.

Main outcome variables
Pain, range of motion (ROM), grip strength and functional outcomes as per volar Barton's fracture using Green O Brien scoring

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221231056999N1**
Registration date: **2023-02-20, 1401/12/01**
Registration timing: **prospective**

Last update: **2023-02-20, 1401/12/01**
Update count: **0**

Registration date
2023-02-20, 1401/12/01

Registrant information

Name
M Aamir

Name of organization / entity
RESnTEC, Institute of Research

Country
Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-01, 1401/12/10

Expected recruitment end date
2023-12-30, 1402/10/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of treatment of Volar Barton fracture with T plate using distal end screws and without distal end screws

Public title
Comparison of treatment of Volar Barton fracture with T plate using distal end screws and without distal end screws
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients having closed volar Barton's fracture with Mehara classification types-1 & II. Presenting within 5 days of fracture.
Exclusion criteria:
Patients with infections, extensive comminution, open fracture with extensive soft tissue damage or contamination, neurological deficit, head injury or major vascular injury, ipsilateral upper limb trauma or those non-compliant to postoperative physiotherapy and follow up. Patients with severe osteoporosis or those with reduced functional requirement of wrist were also excluded.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients were randomly allocated to either T plate using distal end screws or T plate without distal end screws. The lottery method will be performed for randomization. A total of 60 paper slips will be folded and mixed in a lottery box. Then these 60 slips will be randomly divided in to either Group-1 (T plate using distal end screws) or Group-2 (T plate without distal end screws). Equal number of patients will be randomly allocated to both groups (30 in each group).
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
Institutional Review Board, King Edward Medical University
Street address
New Anarkali
City
Lahore
Postal code
54700
Approval date
2020-11-14, 1399/08/24
Ethics committee reference number
843/RC/KEMU

Health conditions studied

1

Description of health condition studied
Volar barton Fracture
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Functional outcome as per Green & O'Brien Score. This is an examiner-rated assessment of pain, functional status, range of motion, and grip strength. Each of the 4 parameters is given a weighting of 25 points, giving a total score of 100. With excellent being 90 to 100, good 80 to 89, fair 65 to 79, and poor <65.
Timepoint
0-days, 14th day, 28th day, 90th day.
Method of measurement
functional outcomes as per Green & O'Brien Scoring

2

Description
Pain, healing and callous formation
Timepoint
0-days, 14th day, 28th day, 90th day.
Method of measurement
Clinical and physical examination

Secondary outcomes

empty

Intervention groups

1

Description
The Modified Henry approach (Trans-FCR) was used to expose the fracture. Skin incision was made over flexor Carpi radialis tendon and incising the tendon sheath. FCR tendon was exposed which was retracted ulnar ward then the far side of the tendon sheath was incised to expose flexor policis longus tendon.the tendon was also retracted ulnar ward. The muscle fibres of pronator

quadratus were incisedalong its radial side to expose the fracture. The 3.5mm T-Plate was used after proper reduction of fracture. T plate using distal end screws was used. Wound was closed in reverse fashion layer by layer.

Category

Treatment - Surgery

2

Description

The Modified Henry approach (Trans-FCR) was used to expose the fracture. Skin incision was made over flexor Carpi radialis tendon and incising the tendon sheath. FCR tendon was exposed which was retracted ulnar ward then the far side of the tendon sheath was incised to expose flexor policis longus tendon.the tendon was also retracted ulnar ward. The muscle fibres of pronator quadratus were incisedalong its radial side to expose the fracture. The 3.5mm T-Plate was used after proper reduction of fracture. T plate without distal end screws was used. Wound was closed in reverse fashion layer by layer.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Orthopedics unit II Mayo Hospital Lahore, Pakistan

Full name of responsible person

Muhammad Zarak Awais

Street address

Anarkali

City

Lahore

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54700

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mayo Hospital, Lahore

Full name of responsible person

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Email

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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

Mayo Hospital, Lahore

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

RESnTEC

Full name of responsible person

Muhammad Aamir

Position

Research Consultant

Latest degree

Bachelor

Other areas of specialty/work

Biostatistics

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable