

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

Phone

+92 321 6801143

Email address

aamir@resntec.com

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 pollicis longus tendon.the tendon was also retracted ulnar ward. The muscle fibres of pronator

quadratus were incised along 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 pollicis longus tendon. The tendon was also retracted ulnar ward. The muscle fibres of pronator quadratus were incised along 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

Postal code

54700

Phone

+92 312 6145131

Email

zarakkhan76.zk@gmail.com

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

Mayo Hospital, Lahore

Full name of responsible person

Muhammad Zarak Awais

Street address

Anarkali

City

Lahore

Postal code

54700

Phone

+92 312 6145131

Email

zarakkhan76.zk@gmail.com

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

Street address

Street No.1

City

Bahawalpur

Province

Punjab

Postal code

63100

Phone

+92 321 6801143

Email

aamir@resntec.com

Person responsible for scientific 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
Street address
Street No.1
City
Bahawalpur
Province
Punjab
Postal code
63100
Phone
+92 321 6801143
Email
aamir@resntec.com

Person responsible for updating data

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
Street address
Street No.1

City
Bahawalpur
Province
Punjab
Postal code
63100
Phone
+92 321 6801143
Email
aamir@resntec.com

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