

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing outcome of forearm diaphyseal fractures that treated by selective screw placement compression plating (4cortex) with whole screw placement in patients older than 18 years

Protocol summary

Summary

In this trial, 124 patients above 18 years old with closed forearm diaphyseal fractures type A and B (OTA), will be entered and will be operated randomly in two groups of 64 patients. In one group fixation with plate and selective screw fixation and in another group fixation with plate and whole screw placement will be done. Patients post op follow up is at 3, 6, 12 and 16 weeks after surgery and rate of infection, nonunion, time of union will be compared between two groups. A union criterion is healing of 3 cortex of 4 cortex of bone without localized tenderness.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010144940N1**

Registration date: **2010-11-28, 1389/09/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-11-28, 1389/09/07

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Jondi Shapour University of Medical Sciences

Expected recruitment start date

2009-04-21, 1388/02/01

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing outcome of forearm diaphyseal fractures that treated by selective screw placement compression plating (4cortex) with whole screw placement in patients older than 18 years

Public title

Adult forearm diaphyseal fracture fixation with plate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients above 18 years old with closed diaphyseal forearm fractures type A and B (OTA).
Exclusion criteria: patients above 70 years or under 18 years old, type C (OTA) fractures, open fractures.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Jondi Shapour University of Medical Sciences

Street address

Golestan street

City

Ahwaz

Postal code

Approval date

2010-01-29, 1388/11/09

Ethics committee reference number

4513//8/20/پ

Health conditions studied

1

Description of health condition studied

Forearm diaphyseal fractures

ICD-10 code

S52.4

ICD-10 code description

Fracture of shafts of both ulna and radius

Primary outcomes

1

Description

union

Timepoint

12 and 16 weeks after surgery

Method of measurement

physical exam and radiography

Secondary outcomes

1

Description

Time of union

Timepoint

12 and 16 weeks after surgery

Method of measurement

time of union according to radiography and physical exam

2

Description

infection

Timepoint

3, 6, 12 and 16 weeks after surgery

Method of measurement

sign of infection such as erythema, tenderness, discharge

Intervention groups

1

Description

fixation with plate and selective screw placement

Category

Treatment - Surgery

2

Description

fixation with plate and whole screw placement

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini and Razi hospital of Ahwaz

Full name of responsible person

Street address

Azadegan street

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy ahwaz Jondi Shapour University of Medical Sciences

Full name of responsible person

Dr. Abdolhosein Mehdinasab

Street address

Imam khomeini hospital

City

Ahwaz

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research deputy ahwaz Jondi Shapour University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty