

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of two Surgical Methods , External Fixator and Pin & Plaster in Treatment of Distal Radius Fractures

Protocol summary

Summary

The design study is a randomized intervention (comparing two surgical methods) Objective: Comparison between external fixator and pins & plasters in the treatment of distal radius fractures in patients referred to Imam Khomeini Hospital Sari Inclusion criteria: Patients should have bone maturation (at least 18 years of age), have distal radius fractures , the range of age between 18 and 70 years and don't have any systemic disease that can interfere in the surgical treatment such as osteoporosis. Exclusion criteria: patients with diseases interfering surgical treatment , age more than 70 or under 18 or have nerve involvement before surgery , have a history of previous fracture in the same radius and patients tend to have may not participate in the study were excluded In this study, we select 100 samples. The 100 patients randomly divided into two groups of 50 patients each are under a kind of surgery are mentioned. a study of 100 cases of distal radius fractures were made, 50 patients with external fixator technique and 50 patients with pins and plaster technique underwent surgery and eventually will compare patient information And in this comparison is done within six months Primary Outcome: Based on previous studies seem who were treated by percutaneous fixation have earlier return to their daily routine but the number of pins and plaster studies have preferred.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103072798N2**

Registration date: **2011-05-24, 1390/03/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-05-24, 1390/03/03

Registrant information

Name

Masoud Shayestehazar

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2011-01-20, 1389/10/30

Expected recruitment end date

2011-07-21, 1390/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two Surgical Methods , External Fixator and Pin & Plaster in Treatment of Distal Radius Fractures

Public title

Comparison of two Surgical Methods in Treatment of Hand Fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients should have bone maturation (at least 18 years of age), have distal radius fractures , the range of age between 18 and 70 years and don't have any systemic disease that can interfere in the surgical treatment such as osteoporosis. Exclusion criteria: patients with diseases interfering surgical treatment , age morethan 70 or under 18 or have nerve involvement before surgery ,have a history of previous fracture in the same radius and patients tend to have may not participate in the study were excluded

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Mazandaran University of Medical Sciences

Street address

Building No.2 , Mazandaran University of Medical Sciences,moallem square

City

Sari

Postal code

Approval date

2011-01-19, 1389/10/29

Ethics committee reference number

89-144

Health conditions studied

1

Description of health condition studied

Distal Radius Fractures

ICD-10 code

S52.5

ICD-10 code description

Fracture of lower end of radius

Primary outcomes

1

Description

malunion

Timepoint

6 Month Follow

Method of measurement

Hand Radiography

Secondary outcomes

1

Description

Wrist Motion Limitation

Timepoint

6 month

Method of measurement

Examination

2

Description

Painfulness

Timepoint

6Month

Method of measurement

Examination

3

Description

Nerve Damage

Timepoint

6Month

Method of measurement

Examination

Intervention groups

1

Description

Control:50 Patients with Pins and Plaster Technique underwent Surgery

Category

Treatment - Surgery

2

Description

Intervention: 50 patients with external fixator technique underwent surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hospital of Sari

Full name of responsible person

Street address

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Ahmadali Enayati

Street address

Vice- Chancellor of Research and Thecnology of
Mazandaran University of Medical Sciences

City

Sari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran 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

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr masoud Shayestehazar

Position

Orthopedic specialist

Other areas of specialty/work

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Masuod Shayestehazar

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Web page address

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

