

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison outcome of volar plate, external fixator and multi pinning for intra articular distal radius fracture treatments

Protocol summary

Study aim

Choosing the right treatment method for fractures distal radius

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

In this clinical trial, all patients who undergo surgery in Hospitals , Babol University of Medical Sciences with a diagnosis of Radial Distal Fractures underwent one of three methods of external fixation, external fixator, Kei wire, are included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 65-95 years Patients with closed fractures and intra-articular distal radius that needed to be fixed surgery Informed consent of patient in the study. Exclusion criteria: Non-traumatic pathologic fractures caused by tumors, severe underlying disease at the same time ipsilateral upper extremity fractures Patient dissatisfaction Sudeck's atrophy and Women over 50 years who have osteoporosis radiography.

Intervention groups

Group 1 by external fixation, Group 2 by external fixator with pinning and Group 3 treated was with Kei wire.

Main outcome variables

Rate of union; Infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190221042782N1**

Registration date: **2019-04-18, 1398/01/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-18, 1398/01/29**

Update count: **0**

Registration date

2019-04-18, 1398/01/29

Registrant information

Name

Seyyed Mokhtar Esmailnejadganji

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-20, 1397/10/30

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison outcome of volar plate, external fixator and multi pinning for intra articular distal radius fracture treatments

Public title

Comparison outcome of fractures of the distal radius bone between the two surgical methods of unstable fractures of the distal radius bone between the two surgical methods

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-65 years Intra-articular distal radius fractures caused by trauma

Exclusion criteria:

Non-traumatic pathologic fractures caused by tumors
Severe underlying disease At the same time ipsilateral upper extremity fractures Patient dissatisfaction
Sudeck's atrophy Women over 50 years who have osteoporosis radiography

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

These patients using random selection based on the application online <http://www.graphpad.com/quickcalcs/randomize1/> will be divided into three groups. The use of external fixation technique for Group 1, with external fixator pins for Group 2 and Group 3 will be considered for long wire.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will not be aware of the treatment they are taking, and this will be blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

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Approval date

2019-01-20, 1397/10/30

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.246

Health conditions studied**1****Description of health condition studied**

Distal radius fracture

ICD-10 code

S52.5

ICD-10 code description

Fracture of lower end of radius

Primary outcomes**1****Description**

Range of motion of wrist

Timepoint

Immediately after surgery, Ten days after surgery, then the sixth and the Twenty-one and the forty- second weeks after surgery

Method of measurement

Through the examination with handheld goniometer

2**Description**

Determination Radio graphic parameters

Timepoint

Immediately after surgery, Ten days after surgery, then the sixth and the Twenty-one and the forty- second weeks after surgery

Method of measurement

Measurement reference markers in the radiographic image

Secondary outcomes**1****Description**

Pain severity

Timepoint

Twenty-one, forty-second weeks after surgery

Method of measurement

By Visual Analogous Scale questionnaire

2**Description**

Pin tract infection

Timepoint

Twenty-one, forty-second weeks after surgery

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: In patients with external fixation using two pins 5/2 mm Schanz pins in the second metacarpal and two 5.3 mm in radius, proximal to the fracture. These pins are connected to each other and the firm. After creating this reduction in the frame and lateral C-arm and Anteroposterior will be controlled.

Category

Treatment - Surgery

2

Description

Intervention group: In patients with external fixator with pinning depending on the patient's need, 2 or 3 pins will also be used for fixation of the fracture site.

Category

Treatment - Surgery

3

Description

Control group: In patients treated with closed reduction of fracture when the wire just under anesthesia and fixation with pins (depending on the shape of fracture 3 or 4 pins) control and reduction and fixation with AP and lateral radiography C_arm during surgery and after surgery is controlled.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Shahid Beheshti Hospital

Full name of responsible person

Dr. Seyyed Mokhtar Esmailnejadganji

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2

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital, Babol

Full name of responsible person

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Recruitment center

Name of recruitment center

Shahid Yahyanejad Hospital in Babol

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

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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

Babol 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

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Seyyed Mokhtar Esmailnejadganji

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available