Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison outcome of volar plate, external fixator and multi pining 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
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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 pining 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

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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 Esmaeilnejadganji

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Name of recruitment center
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Sponsors / Funding sources

1

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Name of organization / entity
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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

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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