Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of radiologic changes of unstable fractures of the distal radius bone using of three cross pin with 4 pin trans-radioulnar

Protocol summary

Summary

The aim of this study is to evaluate the radiologic changes of treatment of unstable distal radius fractures using three cross pin compared with 4 pins trans radioulnar. The sample size will be 50 patients. In a randomized clinical trial, 50 patients with age of 18-65 years old with distal radius fracture will be assigned into two surgical methods of three cross pin or 4 pins trans radioulnar. All the patients will be examined and taken radiography immediately after the operation and 6, 12 and 24 weeks after the operation. Then the outcome measures including the pain severity, radiography measures and wrist range of motion will be compared between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112727797N1**
Registration date: **2016-11-27, 1395/09/07**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-11-27, 1395/09/07

Registrant information

Name

Masoud Bahrami Ferydoni

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of radiologic changes of unstable fractures of the distal radius bone using of three cross pin with 4 pin trans-radioulnar

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18-65 years; patients with closed fractures and intra-articular distal radius that needed to be fixed surgery; also informed consent of patient in the study. Exclusion criteria: surgery on wrist; severe underlying disease

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study, 50 patients have been assigned to two groups of intervention and control by using random numbers table

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

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

City

Babol

Postal code

Approval date

2015-08-03, 1394/05/12

Ethics committee reference number

305808/ژ/پ

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, then the sixth and the twelve and the twenty-fourth weeks after surgery

Method of measurement

Through the examination with handheld goniometer

2

Description

Determination radiographic parameters

Timepoint

Immediately after surgery, then the sixth and the twelve and the twenty-fourth weeks after surgery

Method of measurement

Measurement reference markers in the radiographic image

Secondary outcomes

1

Description

Pain severity

Timepoint

Twenty-fourth weeks after surgery

Method of measurement

By Visual Analogus Scale questionnaire

2

Description

Pin tract infection

Timepoint

Six weeks after surgery

Method of measurement

Observation

Intervention groups

1

Description

For patients cross-pin ulnar corner fixator: Pin-third of the ulnar angle into the distal radius.

Category

Treatment - Surgery

2

Description

In patients Trans-ulnoradial pinning: Pin-third the size of 1.5 in the distal is obliquely driven to the fracture site and the fourth pin of size 2 in proximal of to the fracture site is driven cross-ulnar into the radius bone and it will be ended in the cortex of the radius bone.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Babol Shahid Beheshti Hospital

Full name of responsible person
Dr. Masoud Bahrami Ferydoni

Street address
Babol University of Medical sciences- Ganjafrooz street- Babol- Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor of Reaserch and Technology, Babol University of Medical Sciences

Full name of responsible person
Dr.Aliakbar Moghaddamnia

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Babol University of Medical Sciences- Ganjafrooz Street- Babol- Iran

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Babol

Grant name
-

Grant code / Reference number
-

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

Title of funding source
Vice Chancellor of Reaserch and Technology, Babol 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
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Full name of responsible person
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Resident of Orthopedic

Other areas of specialty/work

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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