

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Outcomes of unstable intra articular distal radius fracture using closed reduction, percutaneous pinning and plaster cast compared with closed reduction and plaster cast in patient older than 65 years

Protocol summary

2019-03-11, 1397/12/20

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 a Shahid Beheshti Hospital with a diagnosis of Radial Distal Fractures underwent one of two methods of closure reduction, percutaneous pinning, placement and closure reduction, 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: Surgery on wrist Severe underlying disease Lack of timely referral for follow-up therapy to the orthopedic clinic.

Intervention groups

One group was packed and pinning, and another group was treated with closure and plaster reduction.

Main outcome variables

Rate of union; Infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160508027797N4**

Registration date: **2019-03-11, 1397/12/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-11, 1397/12/20**

Update count: **0**

Registration date

Registrant information

Name

Masoud Bahrami Ferydoni

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3225 6285

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-30, 1397/10/09

Expected recruitment end date

2019-12-30, 1398/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Outcomes of unstable intra articular distal radius fracture using closed reduction, percutaneous pinning and plaster cast compared with closed reduction and plaster cast in patient older than 65 years

Public title

Comparison outcome of unstable 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 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:

Surgery on wrist Severe underlying disease Lack of timely referral for follow-up therapy to the orthopedic clinic

Age

From **65 years** old to **95 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly divided into two groups. In this study, toss to generate a random sequence in the trial will be two groups. So that one of the study groups is Milk and the other is the line, and based on the sample size, the same number of coins will be thrown, and the individuals will be randomly assigned to two groups. Group line patients treated with closed reduction and pinning and milk treated with closed reduction and casting will be.

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

City

Babol

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Mazandaran

Postal code

4716681451

Approval date

2018-12-30, 1397/10/09

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.237

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 three and the sixth 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, then the three and the sixth and the forty- second weeks after surgery

Method of measurement

Measurement reference markers in the radiographic image

Secondary outcomes

1

Description

Pain severity

Timepoint

Forty-second weeks after surgery

Method of measurement

By Visual Analogous Scale questionnaire

2

Description

Pin tract infection

Timepoint

Three weeks after surgery

Method of measurement

Intervention groups

1

Description

Intervention group: In patients reduction and casting, closed reduction of fracture with in the first 24 hours and then by stretching and manipulation under general anesthesia for closed reduction of fracture is tried. After the reduction approved by the ray casting is conducted at casting method does not need to roll the fabric.

Category

Treatment - Surgery

2

Description

Control group: In percutaneous pinning first closed reduction of fracture under general anesthesia in the first 24 hours was (stretching and manipulation attempts at closed reduction of fracture with the help of rolls of fabric to a height of 20 cm below the wrist placed) then 3 pins 2mm diameter entering a pin in the radial styloid volar radius in the arm and the other arm on the dorsal side and one on the ulnar, radial pin total of 3 proved to be, taken. C-arm fluoroscopy control pin will be approved and then took a long chalk.

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Reza Ghadimi

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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

Dr. Masoud Bahrami Ferydoni

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Asistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

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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

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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