

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of titanium elastic nail versus plate and screw fixation in diaphyseal radius and ulna fractures in 10 to 16 years old patients

Protocol summary

Study aim

Comparison of titanium elastic nail versus plate and screw fixation in diaphyseal radius and ulna fractures in 10 to 16 years old patients

Design

The number of patients in each group is 25. The patients will be randomly assigned to one of two different surgical groups using a random number table. All patients will be referred to an orthopedic clinic at two-week intervals. Goniometer measures the range of motion of the forearm and examines the rate of fracture healing using forearm radiography.

Settings and conduct

Patients enter the study according to inclusion criteria. After randomization, they will be operated on in one of the two study groups. They are then examined at specific intervals after surgery to assess forearm range and union rate. The study site is Shahid Bahonar Hospital of Kerman.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 10 to 16 years with diaphyseal fractures of Radius and Ulna bones ;
Exclusion criteria are: Diaphysis fractures of the radius and ulna bones associated with the involvement of radio ulnar joints (Monteggia and Galeazzi). Pathological fractures, re fracture, open fracture

Intervention groups

Investigation of the consequences and complications caused by fixing the fracture of the forearm bones such as the time of welding and the range of motion, etc. by screwing and plaque method, and examining the consequences and effects of fixing the bones of the forearm such as the time of welding and the range of motion By the method of titanium flexible rods

Main outcome variables

range of motion of fore arm after surgery & time of bone union

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200111046080N1**

Registration date: **2020-04-09, 1399/01/21**

Registration timing: **retrospective**

Last update: **2020-04-09, 1399/01/21**

Update count: **0**

Registration date

2020-04-09, 1399/01/21

Registrant information

Name

Reza Khosravi moshizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3216 1439

Email address

khosravireza3@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of titanium elastic nail versus plate and screw fixation in diaphyseal radius and ulna fractures in 10 to 16 years old patients

Public title

comparision of two method of radius and ulna fractures

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with radius and ulna fractures in 10 to 16 years old

Exclusion criteria:

pathlogic fracture refracture methaphyseal fracture

Age

From **10 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization Personal Patients with study characteristics are given a two-digit code. Then, using a table of random numbers, these codes are selected completely randomly, and each patient enters one of the two groups under study.

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**

Ethics Committee of Kerman University of Medical Sciences

Street address

Campus of the University of Medical Sciences.Alavy highway.Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2019-08-31, 1398/06/09

Ethics committee reference number

IR.KMU.AH.REC.1398.075

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

Radius and ulna bone fractures

ICD-10 code

S52

ICD-10 code description

Unspecified fracture of forearm

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

Fore arm range of motion

Timepoint

three months after surgery

Method of measurement

goniometer

2**Description**

Time of union

Timepoint

6 and 10 weeks

Method of measurement

Radiographic asswsment

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group1: Fixation of diaphysis fractures of radius and ulna bones by flexible titanium rods made by Osweh Company of Mashhad

Category

Treatment - Surgery

2**Description**

Intervention group2: Fixation of diaphysis fractures of radius and ulna bones by screw and plate of mini compression plates made by osweh Mashhad company

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid bahonar hospital.kerman medical university

Full name of responsible person

Reza khosravi moshizi

Street address

Shahid bahonar hospital.Gharani avn. kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman 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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Reza khosravi moshizi

Position

professor assistant

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

Contact

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Shahab illka

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Assistant Professor

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

resident

Latest degree

Medical doctor

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available