

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the Treatment of the Distal Radius Fracture with Closed Reduction and Percutaneous Pinning with and without Superficial Radial Nerve Exploration

Protocol summary

Study aim

Comparison of the outcome and complications of the treatment of distal radius fracture with closed reduction and percutaneous pinning with and without radial nerve exploration

Design

A two-arm parallel-group single-blind randomized controlled trial

Settings and conduct

Patients with a distal radius fracture who refers to the emergency department of Shafa Orthopedic Hospital will be identified and in case of providing written consent will be randomly allocated into one of the two study groups (surgery without radial nerve exploration and surgery with radial nerve exploration). Twelve weeks after treatment with closed reduction and percutaneous pinning, the complications and outcome of the surgery will be compared between the two study groups. The patients will be blinded from the type of surgery.

Participants/Inclusion and exclusion criteria

Patients with distal radius fracture and age of more than 18 years will be included in the study after providing the written consent. Patients with a history of distal radius fracture and patients having associated injuries affecting the outcome of treatment will be excluded from the study.

Intervention groups

Group 1: Treatment of distal radius fracture with closed reduction and percutaneous pinning without radial nerve exploration
Group 2: Treatment of distal radius fracture with closed reduction and percutaneous pinning with radial nerve exploration

Main outcome variables

Wrist range of motion; wrist function; pinch strength; pain; first dorsal web sensation; paresthesia; hyperesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190903044677N1**

Registration date: **2019-11-09, 1398/08/18**

Registration timing: **prospective**

Last update: **2019-11-09, 1398/08/18**

Update count: **0**

Registration date

2019-11-09, 1398/08/18

Registrant information

Name

Pouria Tabrizian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3354 2041

Email address

tabrizian.pouria@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Treatment of the Distal Radius Fracture with Closed Reduction and Percutaneous Pinning with and without Superficial Radial Nerve Exploration

Public title

Treatment of the Distal Radius Fracture with Closed Reduction and Percutaneous Pinning without Superficial Radial Nerve Exploration

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of more than 18 years Providing written consent to participate in the study

Exclusion criteria:

A history of distal radius fracture Concomitant injury affecting the outcome of treatment

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using a computer-generated random number list. For this purpose, the patients will be numbered from 1 to 100. Within this range, 50 random numbers will be generated by Excel software. These random numbers will be matched with the patients' numbers, and corresponding patients will be allocated into the case group. The remaining 50 patients will be allocated to the control group. Accordingly, participants will randomly be assigned in a 1:1 ratio into the two study groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients will be blinded from the group assignment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Next to the Milad tower, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-07-01, 1398/04/10

Ethics committee reference number

IR.IUMS.REC.1398.118

Health conditions studied

1

Description of health condition studied

Distal radius fracture

ICD-10 code

M84.333A

ICD-10 code description

Stress fracture, right radius, initial encounter for fracture

Primary outcomes

1

Description

First dorsal web sensation

Timepoint

Before the intervention and two days after the end of intervention

Method of measurement

Patients' clinical examination

2

Description

Paresthesia

Timepoint

Before the intervention and two days after the end of intervention

Method of measurement

Patients' clinical examination

3

Description

Hyperesthesia

Timepoint

Before the intervention and two days after the end of intervention

Method of measurement

Patients' clinical examination

Secondary outcomes

1

Description

Wrist range of motion

Timepoint

Before the intervention and 12 months after the end of intervention

Method of measurement

Goniometer

2

Description

Wrist function

Timepoint

Before the intervention and 12 months after the end of intervention

Method of measurement

DASH questionnaire

3

Description

Pinch strength

Timepoint

Before the intervention and 12 months after the end of intervention

Method of measurement

Dynamometer

4

Description

Pain

Timepoint

Before the intervention and 12 months after the end of intervention

Method of measurement

Visual analogue scale

Intervention groups

1

Description

Intervention group: Treatment of distal radius fracture with closed reduction and percutaneous pinning without superficial radial nerve exploration

Category

Treatment - Surgery

2

Description

Control group: Treatment of distal radius fracture with closed reduction and percutaneous pinning with superficial radial nerve exploration

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Orthopedic Hospital

Full name of responsible person

Pouria Tabrizian

Street address

Mojahedine-eslam Ave.

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tabrizian.p@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abbas Motevalian

Street address

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Phone

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Email

ivco@iums.ac.ir

Web page address

<http://iums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Shafa Orthopedic Hospital

Full name of responsible person

Pouria Tabrizian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shafa Orthopedic Hospital

Full name of responsible person

Pouria Tabrizian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the data associated with this study are sharable upon request, after anonymizing the participants.

When the data will become available and for how long

6 months after the publication of the results

To whom data/document is available

Academic investigators

Under which criteria data/document could be used

The applicant should provide sufficient documents to prove his/her academic identity. Allowed use of the data is dependent on the confirmation of the performers of this study.

From where data/document is obtainable

Dr. Pouria Tabrizian, Shafa Orthopedic Hospital, Mojahedine-eslam Ave., Tehran. Tel: 00982133542041
Email: tabrizian.pouria@gmail.com

What processes are involved for a request to access data/document

Email application for the data request, Evaluation of the request, identification of the applicant, the reason for requesting data, evaluation of the provided reasons, sending data through email in case of confirming the provided reasons.

Comments