Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the functional and radiological outcomes of arthroscopic-assisted (AA) and fluoroscopic-assisted (FA) reduction of Intra-articular fracture of distal radius

Protocol summary

Study aim

Evaluation of functional and radiological results of intra-articular distal radius fracture (DRF) treatment with arthroscopic and fluoroscopic aid and comparison of two methods with each other.

Design

Single center, two arm parallel groups, randomized trial with blinded postoperative functional evaluation, on 60 patients. R software was used to randomization.

Settings and conduct

This study is being performed at Taleghani Hospital. The patients are randomly divided into two equal groups. In the ORIF group, all fractures will be reduced through the Henry approach and fixed by VLP, fluoroscopically. In another group, based on the surgeon's decision, patients may have undergone ORIF with VLP and then additional arthroscopic-assisted reduction (AAR), or AAR using the multiple pins from the beginning. Functional outcomes are evaluated by another surgeon who is blinded to the patient assignment. The radiological results can not be blinded due to differences in surgical procedures.

Participants/Inclusion and exclusion criteria

Patients over 18 years with unilateral, type B3 and C, intra-articular DRF, who have the possibility of follow-up for evaluation of functional and radiological results for at least 1 year.

Intervention groups

Wrist arthroscopy will be performed to achieve the reduction of intra-articular DRF or correct that, and to assess and treat the accompanying soft tissue injuries.

Main outcome variables

Functional outcomes will be evaluated in the 3rd and 12th months postoperatively, and include VAS, DASH, PRWE, grip strength and ROM. The last two are expressed as a percentage of the opposite side. Radiological outcomes will be evaluated in the 12th months postoperatively, and include the radial inclination, ulnar variance, radiocarpal tilt, SL and CL angles which will be calculated on AP and LAT radiographs. Intra-articular gap and step will be assessed with a wrist CT-SCAN.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180306038971N1**
Registration date: **2020-05-22, 1399/03/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-22, 1399/03/02**
Update count: **0**

Registration date

2020-05-22, 1399/03/02

Registrant information

Name

Mohammad Ali Okhovatpour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the functional and radiological outcomes of arthroscopic-assisted (AA) and fluoroscopic-assisted (FA) reduction of Intra-articular fracture of distal radius

Public title

Examination of arthroscopic and fluoroscopic assisted methods in the treatment of intra-articular fracture of distal radius

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Intra-articular fracture of distal radius (AO/OTA type B3,C) Age over 18 years

Exclusion criteria:

Open fractures: type 2 and above according to the Gustilo-Anderson classification Concomitant fracture of the ipsilateral upper extremity or the other wrist except the ulnar styloid process fracture Neurovascular alteration such as acute carpal tunnel syndrome Compartment syndrome Previous limitation of movement in the wrist due to neuromuscular diseases or untreated nonunion or malunion of the wrist bones, or other injuries which interfered with the next rehabilitation program The need to use a dorsal plate to fix the fracture

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization for 2 intervention groups. The randomization method will done using software, 30 random numbers for each intervention group. The researcher can not play a role in predicting treatment of the disease, and choosing the type of treatment. random sequence will generate by software. Group 1: 30 Cases and Group 2: 30 cases.

Blinding (investigator's opinion)

Single blinded

Blinding description

To compare the functional outcomes of two methods, patients are examined by an orthopedist who is unaware of their surgical procedure in the 3rd and 12th months after surgery, while wearing long gloves or stockinette

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti university of medical science

Street address

Shahid Beheshti University of Medical Sciences, Yemen St., Arabi St., Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2019-05-31, 1398/03/10

Ethics committee reference number

IR.SBMU.MSP.REC.1398.310

Health conditions studied

1

Description of health condition studied

Intra-articular fracture of distal radius

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Comparison of the effect of surgical procedure on postoperative disability

Timepoint

3rd and 12th months in postoperative follow-up

Method of measurement

Patient-rated wrist/hand evaluation (PRWHE) questionnaire

Secondary outcomes

1

Description

Comparison of the effect of surgical procedure on extra-articular displacement, including radial inclination, radiocarpal tilt and ulnar variance

Timepoint

12th months in postoperative follow-up

Method of measurement

Anteroposterior (AP) and lateral (LAT) wrist radiographs

2

Description

Comparison of the effect of surgical procedure on scapholunate (SL) and capitolunate (CL) angle

Timepoint

12th months in postoperative follow-up

Method of measurement

LAT wrist radiography

3

Description

Comparison of the effect of surgical procedure on intra-articular displacement, including gap and step-off

Timepoint

12th months in postoperative follow-up

Method of measurement

Wrist CT-scan

4

Description

Comparison of the effect of surgical procedure on postoperative pain

Timepoint

3rd and 12th months in postoperative follow-up

Method of measurement

Visual analogue scale (VAS) questionnaire

5

Description

Comparison of the effect of surgical procedure on postoperative disability

Timepoint

3rd and 12th months in postoperative follow-up

Method of measurement

Disabilities of the arm, shoulder and hand (DASH) questionnaire

6

Description

Comparison of the effect of surgical procedure on postoperative hand grip strength

Timepoint

3rd and 12th months in postoperative follow-up

Method of measurement

Dynomometer

7

Description

Comparison of the effect of surgical procedure on postoperative wrist range of motion (ROM)

Timepoint

3rd and 12th months in postoperative follow-up

Method of measurement

Goniometer

Intervention groups

1

Description

Intervention group: Based on the surgeon's decision, patients may have undergone open reduction and internal fixation (ORIF) with volar locking plate (VLP) and then additional arthroscopic assisted reduction (AAR), or AAR using the multiple pinning.

Category

Treatment - Surgery

2

Description

Control group: Patients will be undergone surgery with ORIF using VLP under the fluoroscopic control

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Mohammad Ali Okhovat Pour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice Chancellor for research and technology, Shahid Beheshti University of Medical Sciences

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice Chancellor for research and technology, Shahid Beheshti 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
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Position
Associate professor
Latest degree
Subspecialist
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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 data can be shared potentially after patients became unrecognizable.

When the data will become available and for how long

After completing the results and analyzing the data, access to them is allowed.

To whom data/document is available

This is only available for people working in academic institutions

Under which criteria data/document could be used

After obtaining written permission, the use of the data is permitted with reference to the source.

From where data/document is obtainable

Orthopaedic ward in Taleghani hosopital, next to Shahid Beheshti University of Medical Sciences, Yemen St., Arabi St., Chamran Highway. Tell: 00982123031216 Mohammad Ali Okhovat Pour Tell:00982123031294 e-mail: okhovatpour@gmail.com Yaser Safaei Tell:00989155113937 e-mail: yasersafa@yahoo.com

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

After completing the results and analyzing the data, the use of the data is allowed after the written request.

Comments