

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Comparison of Radius osteotomy and capitate osteotomy in the treatment of Kienbock's disease

#### Protocol summary

##### Summary

Objectives: Variety of surgical techniques have been introduced for the treatment of Kienbock's disease. However, there is no consensus regarding the best therapeutic approach. Here we aim to compare the results of radius osteotomy with capitates osteotomy in these patients. Design: Clinical trial Setting and conduct: A number of 20 patients with the confirmed diagnosis of Kienbock's disease, referred to the Shafa Orthopedic Journal, will be entered into the study. Major inclusion and exclusion Criteria: Inclusion criteria: Radiologic Diagnosis of the Kienbock's disease by a hand surgeons; Exclusion criteria: Incidence of any comorbid disorders that might increase the risk of surgery including cardiovascular disorders, uncontrolled diabetes, rheumatic diseases such as rheumatoid arthritis, cancers, hepatic and renal failure and etc. Main outcome measures: The outcome will be assessed using clinical (range of motion) and paraclinical (X-ray and MRI) measures.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017080335382N2**

Registration date: **2017-08-03, 1396/05/12**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-08-03, 1396/05/12

##### Registrant information

###### Name

Farid Najd Mazhar

###### Name of organization / entity

Shafa orthopedic hospital, Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3354 2000

##### Email address

najdmazhar.f@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research of Iran University of Medical Sciences

##### Expected recruitment start date

2017-10-22, 1396/07/30

##### Expected recruitment end date

2018-10-22, 1397/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Radius osteotomy and capitate osteotomy in the treatment of Kienbock's disease

##### Public title

Comparison of two therapeutic approach in Kienbock's disease

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Radiologic Diagnosis of the Kienbock's disease by a hand surgeons; Exclusion criteria: Incidence of any comorbid disorders that might increase the risk of surgery including cardiovascular disorders, uncontrolled diabetes, rheumatic diseases such as rheumatoid arthritis, cancers, hepatic and renal failure and etc.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**

Target sample size: 20

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double 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 Iran University of Medical Sciences

**Street address**

Next to Milad tower, Hammat Highway

**City**

Tehran

**Postal code****Approval date**

2010-09-23, 1389/07/01

**Ethics committee reference number**

-

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

Kienböck disease of adults

**ICD-10 code**

M93.1

**ICD-10 code description**

Adult osteochondrosis of carpal lunate

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

Range of motion of the wrist and radiological symptoms

**Timepoint**

Months 3, 6 of intervention

**Method of measurement**

Goniometer and X-ray and MRI

**Secondary outcomes**

empty

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

Group 1: Radius osteotomy

**Category**

Treatment - Surgery

**2****Description**

Group 2: Capitate osteotomy

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shafa Orthopedic Hospital

**Full name of responsible person**

Farid Najd Mazhar

**Street address**

Shafa Orthopedic Hospital, Mojahedin Islam Avenue, Shohada Square

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Iran University of Medical Sciences

**Full name of responsible person**

Morteza Naserbakht

**Street address**

Next to Milad tower, Hemmat Highway.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Iran 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**

Shafa Orthopedic Hospital

**Full name of responsible person**

farid Najd Mazhar

**Position**

Orthopedic surgeon/Science committee

**Other areas of specialty/work****Street address**

Shafa Orthopedic Hospital, Mojahedin Islam Avenue,  
Shohada Square

**City**

Tehran

**Postal code****Phone**

+98 21 3354 2000

**Fax****Email**

najdmazhar.f@iums.ac.ir; fnajdmazhar@yahoo.com;  
mirzaeialireza26@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shafa Orthopedic Hospital

**Full name of responsible person**

Farid Najd Mazhar

**Position**

Orthopedic surgeon/ Science committee

**Other areas of specialty/work****Street address**

Shafa Orthopedic Hospital, Mojahedin Islam Avenue,

**City**

Tehran

**Postal code****Phone**

+98 21 3354 2000

**Fax****Email**

najdmazhar.f@iums.ac.ir; fnajdmazhar@yahoo.com;  
mirzaeialireza26@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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Shafa Orthopedic Hospital, Mojahedin Islam Avenue,  
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Tehran

**Postal code****Phone**

+98 21 3354 2000

**Fax****Email**

najdmazhar.f@iums.ac.ir; fnajdmazhar@yahoo.com;  
mirzaeialireza26@gmail.com

**Web page address****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*