

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**

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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