

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing of clinical outcomes of radial shortening and radial shortening combined with vascularized bone graft in patients with early stage of Kienböck's disease

Protocol summary

Summary

The aim of this study is to compare tow surgery methods including radial shortening and radial shortening combined with vascularized bone graft for treatment of early stages of Kienböck's disease. Inclusion criteria include patients 18-65 years whom diagnosed with stages II or IIIa of Kienböck's disease according to the Lichtman criteria and exclusion criteria include any serious medical condition that may interfere with safe study participation. Subjects will be selected from patients who referred to Kashani Hospital (Isfahan, Iran) on years 2013-2014. The target sample size are 24 subjects who assign to radial shortening group or radial shortening combined with vascularized bone graft group one by one. In radial shortening group, an average of 3-mm radial shortening will be done and in radial shortening combined with vascularized bone graft group, concurrent radial shortening and anterior vascularized bone grafts from the dorsal distal radius based on the carpal branch of radial artery will be done. Postoperative immobilization will be applied with a short arm cast for 4 weeks. Pain intensity and range of motion will be assessed by the Mayo Wrist Score before the surgery and 9 months after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404127841N5**
Registration date: **2014-04-18, 1393/01/29**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-18, 1393/01/29

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2013-01-01, 1391/10/12

Expected recruitment end date

2014-05-01, 1393/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of clinical outcomes of radial shortening and radial shortening combined with vascularized bone graft in patients with early stage of Kienböck's disease

Public title

Comparing of two surgical method, radial shortening and vascularized bone graft, in Kienböck's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:18-65 years aged;diagnosed with stages II or IIIa of Kienböck's disease according to the Lichtman criteria;written informed consent. Exclusion criteria: any contraindication for receiving general anesthesia; any serious medical condition that may interfere with safe study participation.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

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

Isfahan University of Medical Sciences

Street address

Hezar jerib Street

City

Isfahan

Postal code

Approval date

2012-10-05, 1391/07/14

Ethics committee reference number

9/3144/3

Health conditions studied

1

Description of health condition studied

Kienböck's disease

ICD-10 code

M92.2

ICD-10 code description

Juvenile osteochondrosis of hand

Primary outcomes

1

Description

Pain intensity

Timepoint

Before surgery and 9 months after surgery

Method of measurement

Mayo Wrist Score

2

Description

Range of motion of wrist

Timepoint

Before surgery and 9 months after surgery

Method of measurement

Mayo Wrist Score

Secondary outcomes

1

Description

Postoperative infection

Timepoint

1 week after surgery

Method of measurement

Physical examination

Intervention groups

1

Description

In first group we use radial shortening up to 3 mm. The level of the osteotomy is at the diaphyseal area, nearly 7 cm proximal to the distal articular surface of the radius bone.

Category

Treatment - Surgery

2

Description

In second group we use radial shortening combined with Vascularized bone graft. We use radial shortening up to 3 mm and the level of the osteotomy is at the diaphyseal area, nearly 7 cm proximal to the distal articular surface of the radius bone.The graft and its pedicle are dissected to the transverse volar carpal artery origin.The bone graft is then placed in an about 4 mm deep hole which is made in middle of lunate bone and was stabilized with a fine 5 mm pin.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Orthopedic ward of Kashani Hospital
Full name of responsible person
Ali Moshgelani
Street address
Hezar jerib Street
City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr Peyman Adibi
Street address
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City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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

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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