

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of the Results of Scaphoid Non-union Treatment with Two Methods "Internal Fixation + Autologous Bone Graft" and "Internal Fixation + Allogenic Umbilical Cord Mesenchymal Stem Cells" in Patients Referred to Dr. Shariati Hospital in 2023

Protocol summary

Study aim

Comparison of the Results of Scaphoid Non-union Treatment (Time taken until Union; Degree of Union; Improvement of Pain, Wrist Range of Motion, Grip Strength and Hand Function; Rate of Surgical Complications and Satisfaction with the Operation) with Two Methods "Internal Fixation + Autologous Bone Graft" and "Internal Fixation + Allogenic Umbilical Cord Mesenchymal Stem Cells"

Design

Non-Randomised Parallel Group Clinical Trial on 501 patients

Settings and conduct

This study is a prospective interventional study that is conducted on patients with Scaphoid Non-union referred to Dr. Shariati hospital. Patient information Including demographic information is recorded in the relevant checklists. The patient is explained about the two treatment methods and the advantages and disadvantages of each method, and the patient chooses one of the treatment methods at his own discretion.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having Scaphoid Non-union; at least 3 months between fracture and surgical treatment; consent of the patient to participate in the study
Exclusion Criteria: Previous Surgery on the Wrist
Presence of Wrist Osteoarthritis
Presence of Accompanying Injury (Fracture in Other Bones of the Wrist)

Intervention groups

Patients undergo one of the following treatments: "Internal Fixation + Autologous Bone Graft"; "Internal Fixation + Allogenic Umbilical Cord Mesenchymal Stem Cells"

Main outcome variables

Time taken until union; degree of union; improvement of

pain, wrist range of motion, grip strength and hand function; rate of surgical complications and satisfaction with the operation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221009056121N1**

Registration date: **2022-12-10, 1401/09/19**

Registration timing: **prospective**

Last update: **2022-12-10, 1401/09/19**

Update count: **0**

Registration date

2022-12-10, 1401/09/19

Registrant information

Name

Ehsan Najafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2267 4390

Email address

ehsan.n.6384@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Results of Scaphoid Non-union Treatment with Two Methods "Internal Fixation + Autologous Bone Graft" and "Internal Fixation + Allogenic Umbilical Cord Mesenchymal Stem Cells" in Patients Referred to Dr. Shariati Hospital in 2023

Public title

Comparison of the Effect of Stem Cells and Bone Grafting in the Treatment of Bone Non-union

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having Scaphoid Non-union At Least 3 Months Between Fracture and Surgical Treatment Consent of the Patient to Participate in the Study

Exclusion criteria:

Previous Surgery on the Wrist Wrist Osteoarthritis Presence of Accompanying Injury (Fracture in Other Bones of the Wrist)

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)

Not randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The Patient is Explained About the Two Treatment Methods "Internal Fixation + Autologous Bone Graft" and "Internal Fixation + Allogeneic Mesenchymal Stem Cells" and the advantages and disadvantages of each of the above methods, And the Patient Chooses One of the Above Treatment Methods at her own Discretion

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences Faculty of Medicine

Street address

Room 604, 6th Floor, Tehran University of Medical Sciences Central Building, Qods St. intersection, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2022-02-12, 1400/11/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1343

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

Scaphoid Non-union

ICD-10 code

S62.009K

ICD-10 code description

Unspecified fracture of navicular [scaphoid] bone of unspecified wrist, subsequent encounter for fracture with nonunion

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

Union of Scaphoid Bone

Timepoint

3, 6, 9, 12, 24, and 48 Months After Surgery

Method of measurement

Antero-posterior and Lateral Radiography of the Wrist

Secondary outcomes**1****Description**

Pain

Timepoint

3, 6, 9, 12, 24, 48 and 96 Months After Surgery

Method of measurement

Visual Analogue Scale

2**Description**

Function
Timepoint
3, 6, 9, 12, 24, 48 and 96 Months After Surgery
Method of measurement
Quick-DASH (Disabilities of the Arm, Shoulder, and Hand score)

3

Description
Time to Union
Timepoint
3, 6, 9, 12, 24, 48 and 96 Months After Surgery
Method of measurement
Week

4

Description
Grip Strength
Timepoint
3, 6, 9, 12, 24, 48 and 96 Months After Surgery
Method of measurement
Jamar Dynamometer

5

Description
Wrist Range of Motion
Timepoint
3, 6, 9, 12, 24, 48 and 96 Months After Surgery
Method of measurement
Clinical Examination (Degree)

6

Description
Surgical Complications
Timepoint
3, 6, 9, 12, 24, 48 and 96 Months After Surgery
Method of measurement
Clinical Examination

7

Description
Satisfaction with Surgery
Timepoint
3, 6, 9, 12, 24, 48 and 96 Months After Surgery
Method of measurement
Ask the Patient

Intervention groups

1

Description
Intervention group: nonunion of the scaphoid bone undergoes internal fixation and allogeneic mesenchymal stem cells of umbilical cord origin implanted in fibrin gel are used to induce union
Category
Treatment - Surgery

2

Description
Control group: nonunion of the scaphoid bone undergoes internal fixation and autologous cancellous bone graft are used to induce union
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Shariati Hospital
Full name of responsible person
Leila Oryadi Zanjani
Street address
Department of Orthopedics, Dr. Shariati Hospital, Jalal Al Ahmad Highway
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leila_zanjani@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Hosein Nabian
Street address
Department of Orthopedics, Dr. Shariati Hospital, Jalal Al Ahmad Highway
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mh-nabian@sina.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Ehsan Najafi
Position
Non-faculty Specialist Doctor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
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Person responsible for updating data

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ehsan.n.6384@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available