

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Two Techniques Of Median To Ulnar Nerve Transfer For Treatment Of High Ulnar Nerve Injuries :A Comparative Study

Protocol summary

Registration timing: **retrospective**

Study aim

Comparing the outcomes of side to side transfer of median nerve to the ulnar nerve with transfer of terminal branch of anterior intraosseous to the deep branch of the ulnar nerve and transfer of sensory nerve of third finger to the superficial branch of the ulnar nerve in patients with proximal ulnar nerve injury

Design

In this double-blinded randomized clinical trial, 40 patients will be randomly assigned to two equal and parallel groups using a random number table.

Settings and conduct

The current will be conducted in 15 khordad hospital. After randomization, the patients will undergo the surgery based on their group. The current study is a double-blind study as follows: the patients and examiner at the last visit will not be informed about the surgical procedure.

Participants/Inclusion and exclusion criteria

patients with high ulnar nerve injury included in the study patients with chronic injury were excluded

Intervention groups

group I (side-to-side group): in this group, side-to-side transfer of median nerve to the ulnar nerve will be performed. group II (AIN-sensory group): in this group, the terminal branch of anterior intraosseous nerve will be transferred to the deep branch of the ulnar nerve associated with transfer of the sensory nerve of the third finger to the superficial branch of the ulnar nerve.

Main outcome variables

motor recovery of intrinsic muscle function

Last update: **2021-05-30, 1400/03/09**

Update count: **0**

Registration date

2021-05-30, 1400/03/09

Registrant information

Name

Masoud Yavari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21889021559

Email address

m_yavari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-20, 1397/12/29

Expected recruitment end date

2020-07-20, 1399/04/30

Actual recruitment start date

2019-03-20, 1397/12/29

Actual recruitment end date

2019-03-20, 1397/12/29

Trial completion date

2020-07-20, 1399/04/30

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170502033783N2**

Registration date: **2021-05-30, 1400/03/09**

Scientific title

Two Techniques Of Median To Ulnar Nerve Transfer For Treatment Of High Ulnar Nerve Injuries :A Comparative Study

Public title

Two Techniques Of Median To Ulnar Nerve Transfer For

Treatment Of High Ulnar Nerve Injuries :A Comparative Study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

acute proximal ulnar nerve injury

Exclusion criteria:

associated nerve injury, concomitant ipsilateral fracture, nerve injury requiring graft, previous CVA leading to paralysis of ipsilateral upper limb

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Actual sample size reached: 30

Randomization (investigator's opinion)

Randomized

Randomization description

In the current study, random number table will be used. At first, a point on the table will be selected randomly. Then, the researcher's finger will move in row or column direction. Thus the first 15 two-digit numbers which will be equal to 30 or less be considered as the numbers of the side-to-side transfer group. Thus the numbers of the patients of the other group will be specified.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Shahid Beheshti University of medical sciences

Street address

Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-06-29, 1399/04/09

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.261

Health conditions studied

1

Description of health condition studied

ulner nerve palsy at the level of elbow

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

DASH score will be used to measure the outcomes of surgery.

Timepoint

one year after the operation

Method of measurement

questionnaire

2

Description

two point discrimination test

Timepoint

one year after the operation

Method of measurement

The test will be performed using a unique device with two needles. The distance between the needle can be adjusted.

3

Description

Semmes Weinstein test

Timepoint

one year after the operation

Method of measurement

the test will be performed using a monofilament.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In this group, transfer of the anterior intraosseous nerve to the deep branch of the ulner nerve and transfer of the sensory nerve of the midle finger to the superficial branch of the ulnar nerve will be performed.

Category

Treatment - Surgery

2

Description

Intervention group: In this group, side to side transfer of the median nerve to the ulnar nerve (H graft) will be performed.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

15th Khordad hospital

Full name of responsible person

Amir Bisadi

Street address

Karim Khan st, Azodi st

City

Tehran

Province

Tehran

Postal code

15987 64514

Phone

+98 21 8890 2155

Email

bisadi_a_md@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Reza Vafai

Street address

Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2387 2206

Email

reza.vafai@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amir Bisadi

Position

fellowship resident

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amir Bisadi

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Person responsible for updating data

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Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The proposal and results will be available upon email request.

When the data will become available and for how long

6 months after publication, the documents will be available upon request.

To whom data/document is available

hand surgeons- plastic surgeons- rehabilitation experts

Under which criteria data/document could be used

not applicable

From where data/document is obtainable

The documents will be available upon request to bisadi_a_md@yahoo.com .

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

The documents will be available upon request to bisadi_a_md@yahoo.com .

Comments