Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

Study aim
Comparing the outcomes of side to side transfer of median nerve to the ulnar nerve with trnasfer 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 tranferred 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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170502033783N2**
Registration date: **2021-05-30, 1400/03/09**
Registration timing: **retrospective**

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)

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+98 21889021559

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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

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
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15987 64514
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+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
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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

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Person responsible for updating data

Contact

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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 uopn 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 doucments will be available upon resuest to bisadi_a_md@yahoo.com .

What processes are involved for a request to access data/document
The doucments will be available upon resuest to bisadi_a_md@yahoo.com .

Comments