

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the Open Carpal Tunnel release with Mini Incision Carpal Tunnel Release in the Carpal Tunnel Syndrome (CTS)

Protocol summary

Study aim

We aimed to make a comparison between the outcomes of the open-CT release and mini-incision CT release in patients with CTS

Design

The protocol of this study was approved by Vice-Chancellor for Research and Technology of Shahid Beheshti University of Medical Sciences, Tehran, Iran. All consents were obtained by surgical residents and attending physicians. This non-randomized clinical trial was consisted of 75 patients with CTS to undergo CTS surgery.

Settings and conduct

The study took place in Shohadaye Tajrish hospital. In this study blinding technique was not applicable.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: numbness in the distribution of the median nerve, nocturnal paresthesias, weakness and atrophy of the thenar muscle, presence of a positive Tinel's and/or Phalen's sign on physical examination and electrodiagnostic findings of moderate to severe disease
Exclusion Criteria: other peripheral neuropathies

Intervention groups

Seventy five patients with CTS who were divided into two groups of 45 and 30 patients to undergo open-CT release or mini incision CT release, respectively. In open-CT release a skin incision is made extending from Kaplan's cardinal line distally to beyond the wrist crease proximally. The transverse carpal ligament is reached through the elimination of the subcutaneous fatty tissue and palmar fascia. Then an incision is made to release the nerve. In mini-incision group 1-cm incision is marked in the palm, beginning at the intersection of Kaplan's cardinal line and a line drawn along the radial border of the third web. The 1.5 cm second skin incision is made on a line between tendons and then after reaching to palmar fascia a tunnel is made under fascia and the fascia and carpal ligament is cut to release the nerve.

Main outcome variables

Pain, satisfaction, return to work, length of scar, paresthesia, grip and opposition strength

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191019045155N3**

Registration date: **2020-02-15, 1398/11/26**

Registration timing: **retrospective**

Last update: **2020-02-15, 1398/11/26**

Update count: **0**

Registration date

2020-02-15, 1398/11/26

Registrant information

Name

Negin Yavari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8802 9600

Email address

negin.yavarii@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-09-06, 1394/06/15

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

2015-09-16, 1394/06/25

Actual recruitment end date

2016-06-21, 1395/04/01

Trial completion date

2016-06-21, 1395/04/01

Scientific title

Comparing the Open Carpal Tunnel release with Mini Incision Carpal Tunnel Release in the Carpal Tunnel Syndrome (CTS)

Public title

Surgical Options of CTS

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Positive Tinel's Electrodiagnostic findings of moderate to severe CTS Weakness and atrophy of the thenar muscle Nocturnal paresthesia Numbness Positive Phalen's sign

Exclusion criteria:

other Peripheral Neuropathies

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University, Shahid Shahriari Square, Daneshjou Boulevard, Shahid Chamran Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2015-07-23, 1394/05/01

Ethics committee reference number

518

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

Carpal tunnel syndrome

ICD-10 code

G56.00

ICD-10 code description

Carpal tunnel syndrome, unspecified upper limb

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

Pain

Timepoint

The patients were visited the day after operation and also after 5 months post-operation.

Method of measurement

by visiting the patients, examining and using VAS method to measure their pain

2**Description**

Satisfaction

Timepoint

The patients were visited the day after operation and also after 5 months post-operation.

Method of measurement

by visiting the patients, examining and questioner

3**Description**

Return to work

Timepoint

The patients were visited the day after operation and also after 5 months post-operation.

Method of measurement

by visiting the patients, examining and questioner

4**Description**

Grip strength

Timepoint

The patients were visited the day after operation and also after 5 months post-operation.

Method of measurement

by visiting the patients, examining

5

Description

Opposition strength

Timepoint

The patients were visited the day after operation and also after 5 months post-operation.

Method of measurement

by visiting the patients, examining

6

Description

Length of scar

Timepoint

The patients were visited the day after operation and also after 5 months post-operation.

Method of measurement

by visiting the patients, examining

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: A skin incision is made extending from Kaplan's cardinal line distally to beyond the wrist crease proximally. The transverse carpal ligament is reached through the elimination of the subcutaneous fatty tissue and palmar fascia. Then an incision is made to release the nerve.

Category

Treatment - Surgery

2

Description

Intervention group 2: 1-cm incision is marked in the palm, beginning at the intersection of Kaplan's cardinal line and a line drawn along the radial border of the third web. The 1.5 cm second skin incision is made on a line between tendons and then after reaching to palmar fascia a tunnel is made under fascia and the fascia and carpal ligament is cut to release the nerve.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-Tajrish hospital

Full name of responsible person

Jalaluddin Khoshnevis

Street address

Tajrish Sq., Tehran, Iran

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1989934148

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Pr_shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Ziaei

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Grant name

Grant code / Reference number

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

No

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

Jalaluddin Khoshnevis

Position

Associate professor of surgery

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery
Street address
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the data will be available under the name of supplementary.

When the data will become available and for how long

All the data will be available after the publication of the article forever

To whom data/document is available

Data will be available to everybody upon request

Under which criteria data/document could be used

Data could be used by other researchers for meta-analysis and systematic review

From where data/document is obtainable

Data will be available as a supplementary file to the published article

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

The data will be available upon request, forever.

Comments