Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Oct 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
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 25719
Email
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
Street address
Tajrish Sq., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 25719
Email
pr_shohada@sbmu.ac.ir
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
Tajrish Sq., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1989934148

Phone
+98 21 25719

Email
pr_shohada@sbmu.ac.ir

Person responsible for scientific 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
Tajrish Sq., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1989934148

Phone
+98 21 25719

Email
pr_shohada@sbmu.ac.ir

Person responsible for updating data

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
Tajrish Sq., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1989934148

Phone
+98 21 25719

Email
pr_shohada@sbmu.ac.ir

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