

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Clinical Trial study for comparison of endoscopic carpal tunnel release in patients with median nerve compressive neuropathy with open method

Protocol summary

Summary

Objective: The aim of the study is comparison of the results of endoscopic carpal tunnel release as a newly introduced method with open carpal tunnel surgery.

Design: This is a parallel controlled trial without no randomization and blinding. **Setting and conducting:** All patients who will meet the inclusion criteria will be enrolled in the study for the endoscopic carpal tunnel surgery (they will be called group A or treatment group). Total sample size of treatment group is 81. For selecting control group (who will be called group B), we will apply the retrospective method among all records of patients who had the open carpal tunnel surgery in hospital data bank from 5-year ago (2007). Total sample size of control group is 95. **Inclusion criteria** are all patients with the history of recurrent or persistent paresthesia in the median nerve territory, worsening of symptoms with hand activity, nocturnal paresthesia and presence of positive Tinnel's and/or Phalen's signs on physical examination and also positive electro-myography. **Intervention** for treatment group is one-portal endoscopic method for carpal tunnel release with Microaire instrument per standard technique will be implemented. **Main outcome** of study is complete hand functional recovery. The variables of study are the pain, paresthesia and grip strength measurement. For measuring of pain we will be used the thermometer visual tool. A standard check list will be used for paresthesia and for grip strength, Jamar dynamometer will be applied.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013040612914N1**

Registration date: **2013-05-18, 1392/02/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-18, 1392/02/28

Registrant information

Name

Shahram Nazerani

Name of organization / entity

Iran University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of research, Iran University of Medical Sciences

Expected recruitment start date

2007-01-01, 1385/10/11

Expected recruitment end date

2012-08-01, 1391/05/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial study for comparison of endoscopic carpal tunnel release in patients with median nerve compressive neuropathy with open method

Public title

Effect of endoscopic surgery in comparison with open method in carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients with the history of recurrent or persistent paresthesia in the median nerve territory, worsening of symptoms with hand activity, nocturnal paresthesia and presence of positive Tinnel's and/or Phalen's signs on physical examination and also positive electro-myography; Exclusion criteria: previous carpal tunnel surgery, incomplete records, trauma, patients' refusal to participate in the study.

Age

From **41 years** old to **64 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **176**

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**

Ethics Committee of Iran University of Medical Sciences

Street address

Firozgar Hospital, Behafarin Ave, Karimkhan Zand St, Vali-Asr Sq

City

Tehran

Postal code**Approval date**

2006-11-20, 1385/08/29

Ethics committee reference number

20/11/2006 452/ع

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

Patients with Carpal Tunnel Syndrome (with positive signs in physical exam and also electro-myography)

ICD-10 code

G56.0

ICD-10 code description

Carpal Tunnel Syndrome

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

Pain

Timepoint

One, three, six months and one year after operation

Method of measurement

Thermometer visual tool

2**Description**

Paresthesia

Timepoint

One, three, six months and one year after operation

Method of measurement

Standard check list

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

Grip strength measurement

Timepoint

One, three and six months and one year after operation

Method of measurement

Jamar dynamometer

Intervention groups**1****Description**

Intervention for treatment group is one-portal endoscopic method for carpal tunnel release with Microaire instrument per standard technique will be implemented. According to the type of intervention (Surgery), it is not any dosage or type of consumption and etc.

Category

Treatment - Surgery

2**Description**

For control group the open surgery method will be applied.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Firozgar General Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Sciences Vice chancellor for research, Iran University
of Medical Sciences

Full name of responsible person

Sabze Ghaba Dr

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Sciences Vice chancellor for research, Iran University
of Medical Sciences, Hemmat Free Way

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Sciences Vice chancellor for research, Iran University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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Position

Associate professor of surgery

Other areas of specialty/work**Street address**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty