

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison the results of surgical treatment for carpal tunnel syndrome in both the classical and minimal invasive Smillie knife in patients with carpal tunnel syndrome

Protocol summary

Summary

This study has been aimed to compare the results of open surgery with minimal invasive surgery by Smillie knife. Inclusion criteria such as failure to respond to non-surgical treatment in patients with carpal tunnel syndrome and exclusion criteria such as neuropathy and radiculopathy were determined. 72 patients (98 procedures) with carpal tunnel syndrome were enrolled and were randomized into two groups: open surgery (46 cases) and minimal invasive surgery (52 cases) using Smillie knife and Clinical improvement were compared between the two group by the Boston questionnaire, pain, paresthesia, return to daily activities and scar surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015053110492N1**

Registration date: **2015-07-12, 1394/04/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-12, 1394/04/21

Registrant information

Name

Afshin Ahmadzadeh Heshmati

Name of organization / entity

Kerman university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 34 1247 1551

Email address

dr.heshmati@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the results of surgical treatment for carpal tunnel syndrome in both the classical and minimal invasive Smillie knife in patients with carpal tunnel syndrome

Public title

Comparison the results of surgical treatment for carpal tunnel syndrome in both the classical and minimal invasive Smillie knife

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: non-surgical treatment failure in patients with carpal tunnel syndrome; moderate and severe disease based on nerve-muscle strip. Exclusion criteria: cervical radiculopathy; peripheral nerve lesions; old fractures of the forearm and wrist; congenital bone deformity of the upper limb; rheumatic diseases such as rheumatoid arthritis; minor clashes in the nerve strip; neuropathy

Age

From **25 years** old to **78 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **98**

Randomization (investigator's opinion)

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**

Kerman University of Medical Sciences Ethics
Committee

Street address

In front of Beast clinic- Somaye intersection -Kerman

City

kerman

Postal code**Approval date**

2013-01-20, 1391/11/01

Ethics committee reference number

k/93/157

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

Carpal Tunnel Syndrom

ICD-10 code

G56.0

ICD-10 code description

Carpal tunnel syndrome

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

pain

Timepoint

Before surgery, after five day,two week , six weeks, three
and six month of surgery

Method of measurement

Based on patient response

2**Description**

Paresthesia

Timepoint

Before surgery, after five day,two week , six weeks, three
and six month of surgery

Method of measurement

Based on patient response

3**Description**

Return to daily activities

Timepoint

Before surgery, after five day,two week , six weeks, three
and six month of surgery

Method of measurement

Based on boston form

4**Description**

Scar-site surgery

Timepoint

Five day,two week , six weeks, three and six month of
surgery

Method of measurement

Based on surgeon observation

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

Wound infection

Timepoint

Five day,two week , six weeks, three and six month of
surgery

Method of measurement

Surgeon observation

2**Description**

Nerve injury

Timepoint

Six week after surgery

Method of measurement

Electrodiagnostic finding

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

Intervention group :Minimal invasive surgery by Smillie knife
Category
Treatment - Surgery

2

Description
Control group: Open surgery
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat clinic
Full name of responsible person
Dr Ahmadzadeh Heshmati Afshin
Street address
Research Assistant- Intersection Somayeh-Kerman
City
kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
kerman University of Medical Sciences
Full name of responsible person
Dr Pardakhti
Street address
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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
kerman 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

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Full name of responsible person
Dr Ahmadzadeh Heshmati Afshin
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Person responsible for updating data

Contact

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