

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The Effect of intraoperative local Dexamethasone injection in carpal tunnel release on symptoms and EMG-NCV.

Protocol summary

Study aim

Evaluation of the effect of intraoperative dexamethasone injection on symptoms of the disease and EMG-NCV in carpal tunnel release surgery

Design

50 Patients who come to yazd's Shahid Rahnemoon clinic, Khatam Alanbia clinic and Baghaiee poor clinic and present with paresthesia or prick sensation or pain in first second and third hand fingers are suspected to have carpal tunnel syndrome. then they are evaluated by EMG-NCV. The diagnosis is made by delay in distal motor reaction by 4.5 ms and sensory nerve conduction velocity of more than 3.5 ms and have the inclusion criteria are entered the study and divided into 2 groups by the order of their referral by a previously made randomization chart . the surgeon is informed about which patient belongs to which group. In one group the carpal tunnel release surgery is done alone and in the other group during the similar surgery an intraoperative dexamethasone injection is done too.

Settings and conduct

This study is done in yazd's shahid sadoohi and shahid rahnemoon hospitals. this is a double-blinded design study.the patient and the center taking the EMG-NCV records and the colleague gathering the information of the questionnaire from patients are blinded to which patient belongs to which group.

Participants/Inclusion and exclusion criteria

Inclusion criteria : No history of previous major trauma to the wrist; No history of previous carpal tunnel surgery of the hand; Age of less than 65 and more than 25; controlled diabetes; No history of known autoimmune or collagen vascular disease in patient; symptoms of less than 2 years; No history of recent systemic corticosteroid consumption. Exclusion criteria : Median nerve pathologic findings during surgery

Intervention groups

The surgery begins with a volar 4cm longitudinal incision distal to the distal skin crease of wrist in line with the

third web space, then the transverse carpal ligament and 2 cm of distal antebrachial fascia is incised then the floor of the carpal tunnel and the median nerve is explored for other possible pathologies. The different step in two groups is at this time that in the injection group Just before suturing the skin one milli-litter of dexamethasone is injected in flexor tendon sheath and inside the borders of transverse carpal ligament incision and around the median nerve but not inside the nerve. the only difference between the two groups is the injection step that in one group it is done while in the other it is not done.

Main outcome variables

If the symptom resolution and EMG-NCV results are better in the injection group we may be able to higher the satisfaction of patients from the surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171113037432N1**

Registration date: **2018-01-02, 1396/10/12**

Registration timing: **retrospective**

Last update: **2018-01-02, 1396/10/12**

Update count: **0**

Registration date

2018-01-02, 1396/10/12

Registrant information

Name

mohammad motaghii

Name of organization / entity

shahid sadooghi yazd

Country

Iran (Islamic Republic of)

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+98 35 3822 4301

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Recruitment status
Recruitment complete

Funding source
khatam alanbia EMG-NCV institution of yazd

Expected recruitment start date
2017-02-18, 1395/11/30

Expected recruitment end date
2017-11-21, 1396/08/30

Actual recruitment start date
2017-02-18, 1395/11/30

Actual recruitment end date
2017-11-21, 1396/08/30

Trial completion date
empty

Scientific title
The Effect of intraoperative local Dexamethasone injection in carpal tunnel release on symptoms and EMG-NCV.

Public title
The effect of corticosteroid injection in carpal tunnel syndrom

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who come to Yazd's Shahid Rahnemoon clinic, Khatam Alanbia clinic and Baghaiee poor clinic who are suspected to have carpal tunnel syndrome by symptoms. then they are diagnosed by delay in distal motor reaction by 4.5 ms and sensory nerve conduction velocity of more than 3.5 ms in EMG-NCV. Age of less than 65 and more than 25 Doesn't have known autoimmune or collagen vascular disease Symptoms of no more than 2 years No history of recent systemic corticosteroid consumption
Exclusion criteria:
median nerve pathologic condition encountered during surgery

Age
From **25 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
randomization was based on a computer randomized number chart. each patient was granted a randomized

number due to order of referral. the number specifies which group it belongs to.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double-blinded design study.the patient and the center taking the EMG-NCV records and the colleague gathering the information of the questionnaire from patients are blinded to which patient belongs to which group.

Placebo
Not used

Assignment
Parallel

Other design features
none

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahid sadooghi university of medical sciences of yazd

Street address

yazd, alam square

City

yazd

Province

Yazd

Postal code

8915173149

Approval date

2017-10-04, 1396/07/12

Ethics committee reference number

IR.SSU.MEDICINE.REC.1396.117

Health conditions studied

1

Description of health condition studied

Carpal tunnel syndrome

ICD-10 code

G56.0

ICD-10 code description

Carpal tunnel syndrome

Primary outcomes

1

Description

improvement in symptoms

Timepoint

just before surgery and 2 weeks after surgery

Method of measurement

questionnaire value is the sum of numbers given to each symptom and is an integer

2

Description

EMG-NCV records for median nerve

Timepoint

first in one month before surgery and second time 3 months after surgery

Method of measurement

the time that impulse passes through nerve and is measured by milliseconds

Secondary outcomes

empty

Intervention groups

1

Description

Control group : The surgery begins with a 4cm volar skin incision starting from distal to the distal wrist crease in line with the third web space. then transverse carpal ligament and 2cm of distal antebrachial fascia is completely incised and the median nerve is released, the median nerve and the tunnel are explored for possible pathologies, the wound is irrigated and skin is closed.

Category

Treatment - Surgery

2

Description

Intervention group : The surgery begins with a 4cm volar incision starting from distal to the distal wrist crease in line with the third web space. then transverse carpal ligament and 2cm of distal antebrachial fascia is completely incised and the median nerve is released, the median nerve and the tunnel are explored for possible pathologies and the wound is irrigated in this step 1ml of dexamethasone with 4 milligrams in one milliliter concentration is injected in the flexor tendon sheath and in borders of the transverse ligament cuts and spilled around the median nerve, the difference between two study groups is just in this step and other surgical steps are the same for both groups. then the skin is closed.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

shahid rahneemoon hospital

Full name of responsible person

dr. mostafa zare mehrjardi

Street address

Farokhi street, Azadi square, Yazd

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8913893111

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Recruitment center

Name of recruitment center

baghaee poor clinic

Full name of responsible person

dr. mohammad motaghi

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3

Recruitment center

Name of recruitment center

khatam alanba clinics

Full name of responsible person

dr. mostafa zare mehrjardi

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Email

m.zaremehrjardi@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

EMG-NCV institution of khatam alanba clinic

Full name of responsible person

dr. mostafa zare

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8913893111
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m.aremehjrardi@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
EMG-NCV institution of khatam alanba clinic
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 sadooghi univercity of medical sciences
Full name of responsible person
dr. mostafa zare mehrjardi
Position
orthopaedic surgeon
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Full name of responsible person
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Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available