

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jul 2026

### Comparison of effectiveness of ultrasound guided versus blind injection of local corticosteroid on improvement of clinical and electrodiagnostic findings in patients with moderate carpal tunnel syndrome

#### Protocol summary

##### Summary

(1) Objective: Our aim in this study is to compare injection of corticosteroid by palpation and via ultrasound in improving daily function and electro diagnostic indices in patients with moderate carpal tunnel syndrome. (2) Design: In this study fifty patients with carpal tunnel syndrome referred to Imam Reza physical medicine and rehabilitation clinic, Tabriz will be included in the study after qualifying the inclusion and exclusion criteria and obtaining the informed consent . (3) Setting and conduct: Patients will be randomly divided to two groups of twenty five. For randomization we will use computerized randomization with Excel software. Inclusion criteria are confirmed diagnosis of disease using EMG-NCV and unwillingness to have surgery . Exclusion criteria are contraindications for corticosteroid injection, tenar atrophy, surgery or local injection treatments in last six months, severe carpal tunnel syndrome in EMG-NCV and neoplastic or traumatic source of pain. (4) Interventions: Patients will be divided into two groups of local injection of forty mg of methyl prednisolone with and without ultrasound guidance. In intervention group, the trans carpal route will be determined and confirmed by an experienced physical medicine specialist using ultrasound and in-plane approach. In the other group, injection will be performed by approaching palmaris longus muscle without using any other devices. Routine treatments including non-steroid anti inflammatory drugs and wrist splint for 6 weeks will be performed for all patients. (5) Main outcome measures: EMG-NCV criteria and Boston questionnaire scores will be assessed before study and after injection.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201408013217N9**

Registration date: **2015-01-15, 1393/10/25**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-01-15, 1393/10/25

##### Registrant information

###### Name

Fariba Eslamian

###### Name of organization / entity

Tabriz University of Medical Sciences

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##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research of Tabriz University of Medical Sciences

##### Expected recruitment start date

2014-09-23, 1393/07/01

##### Expected recruitment end date

2015-03-20, 1393/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

|                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Comparison of effectiveness of ultrasound guided versus blind injection of local corticosteroid on improvement of clinical and electrodiagnostic findings in patients with moderate carpal tunnel syndrome |                                                                                                                                                                                                                                                                                                                                   |
| <b>Public title</b>                                                                                                                                                                                        | Evaluating the effects of using an ancillary method for performing local injections in patients with moderate carpal tunnel syndrome                                                                                                                                                                                              |
| <b>Purpose</b>                                                                                                                                                                                             | Treatment                                                                                                                                                                                                                                                                                                                         |
| <b>Inclusion/Exclusion criteria</b>                                                                                                                                                                        | Inclusion criteria : Confirmed diagnosis of disease using EMG-NCV; Unwillingness to have surgery. Exclusion criteria : Contraindications for corticosteroid injection; tenar atrophy; surgery or local injection treatments in last six months; severe carpal tunnel syndrome in EMG-NCV; neoplastic or traumatic source of pain. |
| <b>Age</b>                                                                                                                                                                                                 | No age limit                                                                                                                                                                                                                                                                                                                      |
| <b>Gender</b>                                                                                                                                                                                              | Both                                                                                                                                                                                                                                                                                                                              |
| <b>Phase</b>                                                                                                                                                                                               | 3                                                                                                                                                                                                                                                                                                                                 |
| <b>Groups that have been masked</b>                                                                                                                                                                        | No information                                                                                                                                                                                                                                                                                                                    |
| <b>Sample size</b>                                                                                                                                                                                         | Target sample size: 50                                                                                                                                                                                                                                                                                                            |
| <b>Randomization (investigator's opinion)</b>                                                                                                                                                              | Randomized                                                                                                                                                                                                                                                                                                                        |
| <b>Randomization description</b>                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                   |
| <b>Blinding (investigator's opinion)</b>                                                                                                                                                                   | Single blinded                                                                                                                                                                                                                                                                                                                    |
| <b>Blinding description</b>                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                   |
| <b>Placebo</b>                                                                                                                                                                                             | Not used                                                                                                                                                                                                                                                                                                                          |
| <b>Assignment</b>                                                                                                                                                                                          | Parallel                                                                                                                                                                                                                                                                                                                          |
| <b>Other design features</b>                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                   |
| <b>Secondary Ids</b>                                                                                                                                                                                       | empty                                                                                                                                                                                                                                                                                                                             |
| <b>Ethics committees</b>                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                   |
| <b><u>1</u></b>                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                   |
| <b>Ethics committee</b>                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                   |
| <b>Name of ethics committee</b>                                                                                                                                                                            | Ethics committee of Tabriz University of Medical Sciences                                                                                                                                                                                                                                                                         |
| <b>Street address</b>                                                                                                                                                                                      | Ethics committee, Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz                                                                                                                                                                                                                                    |
| <b>City</b>                                                                                                                                                                                                | Tabriz                                                                                                                                                                                                                                                                                                                            |
| <b>Postal code</b>                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                   |
| <b>Approval date</b>                                                                                                                                                                                       | 2014-09-01, 1393/06/10                                                                                                                                                                                                                                                                                                            |
| <b>Ethics committee reference number</b>                                                                                                                                                                   | 9398                                                                                                                                                                                                                                                                                                                              |

|                                                |                                                                                                                                                                       |
|------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Health conditions studied</b>               |                                                                                                                                                                       |
| <b><u>1</u></b>                                |                                                                                                                                                                       |
| <b>Description of health condition studied</b> | Carpal tunnel syndrome                                                                                                                                                |
| <b>ICD-10 code</b>                             | G56.0                                                                                                                                                                 |
| <b>ICD-10 code description</b>                 | Carpal tunnel syndrome                                                                                                                                                |
| <b>Primary outcomes</b>                        |                                                                                                                                                                       |
| <b><u>1</u></b>                                |                                                                                                                                                                       |
| <b>Description</b>                             | EMG-NCV criteria                                                                                                                                                      |
| <b>Timepoint</b>                               | Before study and after the injection                                                                                                                                  |
| <b>Method of measurement</b>                   | By using EMG-NCV device                                                                                                                                               |
| <b><u>2</u></b>                                |                                                                                                                                                                       |
| <b>Description</b>                             | Boston questionnaire                                                                                                                                                  |
| <b>Timepoint</b>                               | Before study and after the injection                                                                                                                                  |
| <b>Method of measurement</b>                   | By using Boston questionnaire                                                                                                                                         |
| <b>Secondary outcomes</b>                      | empty                                                                                                                                                                 |
| <b>Intervention groups</b>                     |                                                                                                                                                                       |
| <b><u>1</u></b>                                |                                                                                                                                                                       |
| <b>Description</b>                             | In intervention group, the trans carpal route will be determined and confirmed by an experienced physical medicine specialist using ultrasound and in-plane approach. |
| <b>Category</b>                                | Treatment - Devices                                                                                                                                                   |
| <b><u>2</u></b>                                |                                                                                                                                                                       |
| <b>Description</b>                             | In the other group, injection will be performed by approaching palmaris longus muscle without using any other devices.                                                |
| <b>Category</b>                                | Treatment - Drugs                                                                                                                                                     |
| <b>Recruitment centers</b>                     |                                                                                                                                                                       |
| <b><u>1</u></b>                                |                                                                                                                                                                       |
| <b>Recruitment center</b>                      |                                                                                                                                                                       |
| <b>Name of recruitment center</b>              |                                                                                                                                                                       |

Imam Reza Hospital  
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Dr. Fariba Eslamiyan  
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Imam Reza Hospital, Daneshgah Square, Tabriz  
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Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice Chancellor for research of Tabriz University of  
Medical Sciences  
**Full name of responsible person**  
Dr. Seyyed Kazem Shakouri  
**Street address**  
Vice Chancellor for research, Tabriz University of  
Medical Sciences, Daneshgah square, Tabriz  
**City**  
Tabriz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice Chancellor for research of Tabriz 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

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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)

*empty*

#### Study Protocol

*empty*

#### Statistical Analysis Plan

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*