

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### The Effectiveness of Tecar Therapy on Improving Pain and Functional Disability of Neck and Shoulder in Patients with Myofascial Pain Syndrome in Upper Trapezius

#### Protocol summary

##### Study aim

Determination of the effect of TECAR therapy on reducing pain and improving neck and shoulder function in patients with myofascial pain syndrome in upper trapezius

##### Design

The study will be conducted as a randomized clinical trial. The patients will be divided to 2 groups of intervention and control using block randomization method. The control group will be under stretching exercises of upper trapezius and taking acetaminophen tablets with Tizanidine tablets. The intervention group will also undergo TECAR therapy, upper trapezius stretching exercises and acetaminophen tablets with Tizanidine tablets.

##### Settings and conduct

The study will be conducted as a randomized clinical trial including all patients aged 18-60 years with upper trapezius muscle myofascial pain syndrome who have pain for at least one month and VAS score greater than 3 and refer to physical medicine and rehabilitation clinic at the specified time. The diagnostic method is based on physical examination. The patients will be divided to 2 groups of intervention and control. All patients will be evaluated for pain and disability through VAS, NDI and SPADI.

##### Participants/Inclusion and exclusion criteria

The study population consisted of all patients 18-60 years old with upper trapezius muscle myofascial pain who had pain for at least one month and VAS score greater than 3 and referred to physical medicine and rehabilitation clinic at the specified time. Exclusion criteria: diseases or conditions that interfere with the desired treatment.

##### Intervention groups

The control group will be under stretching exercises of upper trapezius and taking acetaminophen tablets with Tizanidine tablets. The intervention group will also

undergo TECAR therapy, upper trapezius stretching exercises and acetaminophen tablets with Tizanidine tablets.

##### Main outcome variables

Improving Pain and Functional Disability of Neck and Shoulder

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210623051688N1**

Registration date: **2021-07-22, 1400/04/31**

Registration timing: **prospective**

Last update: **2021-07-22, 1400/04/31**

Update count: **0**

##### Registration date

2021-07-22, 1400/04/31

##### Registrant information

##### Name

Soroush Sadri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3778 9307

##### Email address

soroushsadri@resident.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-23, 1400/05/01

##### Expected recruitment end date

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| 2022-05-22, 1401/03/01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Not blinded                                                                                                             |
| <b>Actual recruitment start date</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Blinding description</b>                                                                                             |
| empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Placebo</b>                                                                                                          |
| <b>Actual recruitment end date</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Not used                                                                                                                |
| empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Assignment</b>                                                                                                       |
| <b>Trial completion date</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Factorial                                                                                                               |
| empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Other design features</b>                                                                                            |
| <b>Scientific title</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Secondary Ids</b>                                                                                                    |
| The Effectiveness of Tecar Therapy on Improving Pain and Functional Disability of Neck and Shoulder in Patients with Myofascial Pain Syndrome in Upper Trapezius                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | empty                                                                                                                   |
| <b>Public title</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Ethics committees</b>                                                                                                |
| The Effectiveness of Tecar Therapy on Improving Pain and Functional Disability of Neck and Shoulder in Patients with Myofascial Pain Syndrome in Upper Trapezius                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>1</b>                                                                                                                |
| <b>Purpose</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Ethics committee</b>                                                                                                 |
| Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Name of ethics committee</b>                                                                                         |
| <b>Inclusion/Exclusion criteria</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Ethics committee of Isfahan University of Medical Sciences                                                              |
| <b>Inclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Street address</b>                                                                                                   |
| Myofascial pain in superior trapezius muscle diagnosed by clinical examination and presence of point trigger and band taut Consent for being included in the study No therapeutic intervention in the recent 30 days Pain for at least 1 month and VAS score higher than 3 Age between 18 to 60 Referral at the appointed time to the Physical Medicine and Rehabilitation clinic                                                                                                                                                                                                                                                                              | Building No. 4, Vice Chancellor for Research and Technology, Isfahan University of Medical Sciences, Hezar Jerib Street |
| <b>Exclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>City</b>                                                                                                             |
| Surgery or Cervical Fracture in past 2 years Pregnancy-Lactation Infection Coagulation disorders Using oral or parenteral corticosteroids Using oral or parenteral narcotics Cervical Myelopathy or Radiculopathy Psychologic disorders or Cognitive Impairments                                                                                                                                                                                                                                                                                                                                                                                               | Isfahan                                                                                                                 |
| <b>Age</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Province</b>                                                                                                         |
| From <b>18 years</b> old to <b>60 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Isfahan                                                                                                                 |
| <b>Gender</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Postal code</b>                                                                                                      |
| Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 7346181746                                                                                                              |
| <b>Phase</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Approval date</b>                                                                                                    |
| 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 2021-06-21, 1400/03/31                                                                                                  |
| <b>Groups that have been masked</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Ethics committee reference number</b>                                                                                |
| No information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | IR.MUI.MED.REC.1400.219                                                                                                 |
| <b>Sample size</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Health conditions studied</b>                                                                                        |
| Target sample size: <b>50</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>1</b>                                                                                                                |
| <b>Randomization (investigator's opinion)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Description of health condition studied</b>                                                                          |
| Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Myofascial Pain Syndrome in Upper Trapezius                                                                             |
| <b>Randomization description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>ICD-10 code</b>                                                                                                      |
| Diagnosis will be done by clinical examination and presence of trigger point and taut band. The patients will be divided to 2 groups of intervention(TECAR THERAPY, drug, exercise) and control (drug and exercise) using block randomization method. After admission of patients to the Physical Medicine and Rehabilitation clinic , The Physiatrist will examine the patient and refer him to the practitioner. The practitioner divided the patients into two groups.(randomization will be done by the practitioner and the examiner is blinded) After intervention, the patient will be examined by the specialist (who is blinded) for the second time. | M79.1                                                                                                                   |
| <b>Blinding (investigator's opinion)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>ICD-10 code description</b>                                                                                          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Myalgia                                                                                                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Primary outcomes</b>                                                                                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>1</b>                                                                                                                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Description</b>                                                                                                      |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Pain and Functional Disability of Neck and Shoulder                                                                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Timepoint</b>                                                                                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Before the intervention, immediately after the end of the intervention and one month after the end of the intervention  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Method of measurement</b>                                                                                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Visual Analogue Scale(VAS)-Neck Disability Index(NDI)-Shoulder Pain and Disability Index(SPADI)                         |

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: TECAR therapy is a long-wave diathermy that is performed for 6 sessions, 2 sessions per week for 3 weeks, for 20 minutes per session.

#### Category

Treatment - Devices

### 2

#### Description

Intervention group: Upper Trapezius stretching exercises 9 times a day (3 times in the morning-3 times noon-3 times at night) and 30 seconds each time

#### Category

Rehabilitation

### 3

#### Description

Intervention group: Taking acetaminophen 325 mg tablets daily with 4 mg tizanidine tablets in the form of taking a quarter tablet in the first 3 nights and then a second tablet every night

#### Category

Treatment - Drugs

### 4

#### Description

Control group: Upper Trapezius stretching exercises 9 times a day (3 times in the morning-3 times noon-3 times at night) and 30 seconds each time

#### Category

Rehabilitation

### 5

#### Description

Control group: Taking acetaminophen 325 mg tablets daily with 4 mg tizanidine tablets in the form of taking a quarter tablet in the first 3 nights and then a second tablet every night

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan University of Medical Sciences

##### Full name of responsible person

Soroush Sadri

##### Street address

Isfahan University of Medical Sciences, Hezar Jerib Street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

##### Phone

+98 31 3668 8138

##### Email

research@mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shaghayegh Haghjooy Javanmard

##### Street address

Building No. 4, Vice Chancellor for Research and Technology, Isfahan University of Medical Sciences, Hezar Jerib Street

##### City

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##### Province

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##### Phone

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##### Email

research@mui.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Soroush Sadri

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Parisa Taheri

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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## Person responsible for updating data

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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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**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available