

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the efficacy of local corticosteroid injection and high-level laser therapy in patients diagnosed with de Quervain's tenosynovitis.

#### Protocol summary

##### Study aim

Determining and comparing the effectiveness of local corticosteroid injection and high-power laser therapy in patients with de Quervain's tenosynovitis.

##### Design

Clinical trial with two parallel groups, bilaterally blind, randomized, phase 3 on 20 patients, random numbers table was used for randomization by block method.

##### Settings and conduct

The population investigated in this study consists of patients with the diagnosis of de Quervain's tenosynovitis who have referred to the physical medicine clinic of Besat Hospital. Patients in group A will undergo high-power laser therapy. In this group, a gallium aluminum arsenide diode laser with a wavelength of 1064 nm, an output power of 8 watts, and an average energy intensity of 4 J/cm<sup>2</sup> will be used. The laser wave is a pulse type with a frequency of 50 Hz and will be applied by scanning method. The total duration of treatment in each session will be 5-7 minutes. All patients will be treated for 3 consecutive weeks (5 sessions). Local corticosteroid injections will be performed for patients in group B. First, an ultrasound of the wrist is performed and the appropriate point for injection is marked. Then, under the sono guide, 1 ml of hydrocortisone and 1 ml of 2% lidocaine are injected at the site of the mark.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Duration of diagnosis is at least 3 months; Age 18-65 years; Minimum pain intensity according to VAS > 3; Exclusion Criteria: History of surgery or recent wrist trauma; Vascular diseases; Corticosteroid treatment currently or within the past 4 months

##### Intervention groups

Patients in group A will undergo high-power laser therapy, 5 sessions of 5 minutes. Patients in group B will be injected with 1 ml of hydrocortisone and 1 ml of 2% lidocaine.

##### Main outcome variables

tendon thickness, pain intensity, quality of life, patient satisfaction with treatment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221228056965N1**

Registration date: **2023-09-06, 1402/06/15**

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

Last update: **2023-09-06, 1402/06/15**

Update count: **0**

##### Registration date

2023-09-06, 1402/06/15

##### Registrant information

##### Name

motahareh pourgholam

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3323 6909

##### Email address

m.akbarikia@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-21, 1402/02/01

##### Expected recruitment end date

2024-04-20, 1403/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Comparing the efficacy of local corticosteroid injection and high-level laser therapy in patients diagnosed with de Quervain's tenosynovitis.

**Public title**  
Comparing the efficacy of laser and injection in de Quervain's tenosynovitis

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
diagnosis of de Quervain's tenosynovitis Duration of diagnosis is at least 3 months Age 18-65 years Minimum pain intensity according to VAS>3.  
**Exclusion criteria:**  
History of recent wrist surgery or trauma Vascular diseases Corticosteroid treatment currently or within the past 4 months

**Age**  
From **18 years** old to **65 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  

- Outcome assessor

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
We made 30 cards and write letter C on 15 for corticosteroid and on the other 15 letter L for the laser therapy group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and open it, based on selected letter ( C or L) patients will be assigned to local corticosteroid injection and high-level laser therapy

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The outcome assessor will be blinded to the treatment group of the patients.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Ethics Committee of Hamedan University of Medical Sciences

**Street address**

Shahid Fahmideh St, Pazhouhesh

**City**

Hamedan

**Province**

Hamadan

**Postal code**

6517838736

**Approval date**

2022-12-03, 1401/09/12

**Ethics committee reference number**

IR.UMSHA.REC.1401.745

## Health conditions studied

### 1

**Description of health condition studied**

de Quervain's tenosynovitis

**ICD-10 code**

M65.4

**ICD-10 code description**

Radial styloid tenosynovitis [de Quervain]

## Primary outcomes

### 1

**Description**

Changes in the intensity of pain in the wrist

**Timepoint**

On arrival, 4 weeks After the intervention, 12 weeks After the intervention

**Method of measurement**

visual analog scale

## Secondary outcomes

### 1

**Description**

Quality of Life

**Timepoint**

On arrival, 4 weeks After the intervention, 12 weeks After the intervention

**Method of measurement**

12- item short form survey

## Intervention groups

### 1

**Description**

"The first Intervention group": high-power laser therapy, in this group, a gallium aluminum arsenide diode laser with a wavelength of 1064 nm, an output power of 8 watts, and an average energy intensity of 4 joules per square centimeter will be used. The laser wave is a pulse type with a frequency of 50 Hz and will be applied by scanning method. The total duration of treatment in each session will be 5-7 minutes. All patients will be treated for 3 consecutive weeks (5 sessions).

#### Category

Rehabilitation

## 2

#### Description

The second Intervention group : "intervention group 2": For patients in this group , local injection of corticosteroids will be performed. First, an ultrasound of the wrist is performed and the appropriate point for injection is marked. Then, under the sono guide, 1 ml of hydrocortisone and 1 ml of 2% lidocaine are injected at the site of the mark.

#### Category

Rehabilitation

## Recruitment centers

## 1

#### Recruitment center

##### Name of recruitment center

Hamadan Besat Hospital

##### Full name of responsible person

Motahareh Pourgholam

##### Street address

Hokama St, Motahari Blvd

##### City

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##### Province

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##### Postal code

4541165148

##### Phone

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##### Fax

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##### Email

motaharehpoorqolam@gmail.com

##### Web page address

## Sponsors / Funding sources

## 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr Shokouhi

##### Street address

Fahmideh St, Pazhouhesh Sq

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Hamedan

##### Province

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##### Postal code

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##### Phone

+98 81 3252 0182

##### Email

vc\_research@umsha.ac.ir

##### Web page address

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

##### Full name of responsible person

Motahareh Pourgholam

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Physical Medicine

##### Street address

Hokama St, Besat Hospital

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6514845411

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

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**Position**

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**Latest degree**

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**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**

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

**Statistical Analysis Plan**

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

**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

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Motahareh Pourgholam

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**