

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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/cm² 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

Hamedan

Province

Hamadan

Postal code

4541165148

Phone

+98 991 788 8751

Fax

+98 81 3265 1515

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

City

Hamedan

Province

Hamadan

Postal code

6517838736

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

City

Hamedan

Province

Hamadan

Postal code

6514845411

Phone

+98 81 3264 0033

Email

M.akbarikia@yahoo.com

Person responsible for scientific 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

City

Hamedan

Province

Hamadan

Postal code

6514845411

Phone

+98 81 3264 0033

Email

M.akbarikia@yahoo.com

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

Hokama St, Besat Hospital

City

Hamedan

Province

Hamadan

Postal code

6514845411

Phone

+98 81 3264 0033

Email

M.akbarikia@yahoo.com

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