Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
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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 survay

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
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Sponsors / Funding sources

1

Sponsor

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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
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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