Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of the effects of high power laser and mirror therapy on type I complex regional pain syndrome in the hand area

Protocol summary

Study aim
The effect of high power laser and mirror therapy on complex regional pain syndrome type 1 in the hand area

Design
This study is a randomized, single-blind, placebo-controlled clinical trial. Available sampling method and patients are randomly divided into two groups depending on the high power laser and mirror therapy and Placebo laser and mirror therapy.

Settings and conduct
The patients in question attend the research center of Tarbiat Modarres University and then, after controlling the inclusion and exclusion criteria of the study, fill in the informed consent form for inclusion in the study. After initial clinical evaluations, they are divided into intervention and control groups. Clinical evaluations are performed again after the treatment sessions.

Participants/Inclusion and exclusion criteria
Inclusion criteria: existence of complex regional pain syndrome in the hand; swelling in the affected hand; having persistent pain that is not commensurate with the cause of the accident. Exclusion criteria: pregnancy; infection; patients with history of stroke; radiotherapy in the last 6 months.

Intervention groups
In this study, patients are divided into two groups of intervention and control. In the intervention group, first a high-power laser is shone on the hand area, then mirror therapy is performed as a range of motion exercises for the joints of the hand. In the control group, the high-power laser is performed as a placebo and then the mirror therapy is performed as a range of motion exercises for the joints of the hands.

Main outcome variables
Pain level; hand function level; range of motion; swelling level; muscle activity level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210724051966N1**
Registration date: **2022-02-07, 1400/11/18**
Registration timing: **prospective**

Last update: **2022-02-07, 1400/11/18**
Update count: **0**

Registration date
2022-02-07, 1400/11/18

Registrant information

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Farhan Khorramdel
Name of organization / entity
The university of Tarbiat Modares
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-06, 1400/12/15

Expected recruitment end date
2022-08-06, 1401/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effects of high power laser and mirror therapy on type I complex regional pain syndrome in the hand area

Public title
Evaluation of the effects of high power laser and mirror therapy on type I complex regional pain syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis by a neurologist or orthopedist of a complex regional pain syndrome in the participant's hand Men and women with type 1 complex regional pain syndrome based on the Budapest standard The patient's hand is involved Having constant pain that is not commensurate with the accident that caused it There is edema or swelling in the hand relative to the healthy side

Exclusion criteria:
Pregnancy Infection Radiotherapy in the last 6 months cancer Patients with stroke People's unwillingness to continue treatment for any reason

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are randomly assigned to the study or control group by selecting one of the envelopes in the package

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, only participants in the study are blinded. In both groups, mirror therapy and laser therapy are performed, but in the control group, instead of laser, there is only red light.

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tarbiat modares University

Street address
Tarbiat Modarres University, Jalal al Ahmad Ave., Nasr Bridge

City
Tehran

Province
Tehran

Postal code
1411713116

Approval date
2021-12-26, 1400/10/05

Ethics committee reference number
IR.MODARES.REC.1400.260

Health conditions studied

1

Description of health condition studied
Complex regional pain syndrome

ICD-10 code
G90.5

ICD-10 code description
Complex regional pain syndrome I (CRPS I)

Primary outcomes

1

Description
Pain level changes

Timepoint
Measurement of pain at the beginning of the study (before the intervention) and at the end of treatment sessions (seven sessions and three sessions per week for a total of fourteen days after the intervention)

Method of measurement
Visual analogue scale

2

Description
Hand function changes

Timepoint
Measurement of changes in hand function at the beginning of the study (before the intervention) and at the end of treatment sessions (seven sessions and three sessions per week for a total of fourteen days after the intervention)

Method of measurement
Fugl-Meyer Evaluation Scale

3

Description
Hand swelling changes

Timepoint
Measurement of changes in hand swelling at the beginning of the study (before the intervention) and at the end of treatment sessions (seven sessions and three

sessions per week for a total of fourteen days after the intervention)

Method of measurement

Measurement by Figure of eight method

4

Description

Range of motion

Timepoint

Measurement of range of motion at the beginning of the study (before the intervention) and at the end of the treatment sessions (seven sessions and three sessions per week for a total of fourteen days after the intervention)

Method of measurement

Goniameter

5

Description

The amount of muscle activity

Timepoint

Measurement of muscle activity at the beginning of the study (before the intervention) and at the end of the treatment sessions (seven sessions and three sessions per week for a total of fourteen days after the intervention)

Method of measurement

Electromyography device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: High-power laser with K-laser brand with a power of 5 watts with a dose of 20 joules per square centimeter and a cross-sectional area of 1 cm in 3 phases in the entire hand area. Seven sessions and 3 sessions per week of this intervention is performed. Then, mirror therapy is performed with Range of motion exercise of the hand joints.

Category

Treatment - Other

2

Description

Control group: Red light radiation is done in 3 phases and in the whole hand area. Seven sessions and 3 sessions per week of this intervention. Mirror therapy is then performed with Range of motion exercise of the hand joints.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

The University of Tarbiat Modares

Full name of responsible person

Farhan Khorramdel

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Tarbiat modares

Full name of responsible person

Yaghoob Fatolahi

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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

The University of Tarbiat modares

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
The University of Tarbiat Modares

Full name of responsible person
Farhan Khorramdel

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

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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