

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of the wristband with low-level laser therapy in comparison with wristband alone in reducing pain in patients with the wrist ganglion cyst

Protocol summary

Study aim

Determining the effect of low power laser on reducing pain caused by ganglion cysts of the wrist

Design

A randomized single-blinding clinical trial with the control group, with parallel groups, phase 3 on 60 patients

Settings and conduct

In this study, 60 patients with ganglion cysts of the wrist referred to Al-Zahra Hospital will be included in the study and will be randomly divided into two groups. Due to the intervention method, the study is single-blind. Both groups will receive wristbands. The intervention group is also treated with the low-level laser. In the control group, patients will be received a zero-watt laser in the same way. Patients' pain is assessed before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having wrist pain caused by the ganglion cyst and satisfaction to participate in the study. Exclusion criteria include intra-articular corticosteroid injection in the last 6 months, use of low-level laser therapy to treat cyst in the last 6 months, other joint disorders besides ganglion cyst, history of distal forearm and wrist fractures, having polyneuropathy and peripheral nerve involvement (Ulnar, Radial, Median), having rheumatic diseases, and have a history of recent trauma in the past two months.

Intervention groups

All patients use a wristband. In the intervention group, patients receive laser by "FLOWER" method as a point in the middle of the ganglion cyst with intensity of 10 J and 4 points around it with an intensity of 5 J by a 0.5 watt power device. In the control group, patients will receive a zero-watt laser in the same way.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120729010439N4**

Registration date: **2020-12-23, 1399/10/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-23, 1399/10/03**

Update count: **0**

Registration date

2020-12-23, 1399/10/03

Registrant information

Name

Babak Vahdatpour

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 5555

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Evaluation of the effect of the wristband with low-level laser therapy in comparison with wristband alone in reducing pain in patients with the wrist ganglion cyst
Public title	The effect of low level laser therapy in pain relief of patients with wrist ganglion cyst
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Having wrist pain caused by the ganglion cyst Satisfaction to participate in the study
Exclusion criteria:	Intra-articular corticosteroid injection in the last 6 months Use of low-level laser therapy to treat cyst in the last 6 months Other joint disorders besides ganglion cyst History of distal forearm and wrist fractures Having polyneuropathy and peripheral nerve involvement (Ulnar, Radial, Median) Having rheumatic diseases Have a history of recent trauma in the past two months
Age	No age limit
Gender	Both
Phase	3
Groups that have been masked	- Participant - Investigator
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	We randomly select 60 eligible patients. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of the two study groups.
Blinding (investigator's opinion)	Single blinded
Blinding description	In this study, due to the fact that the intervention group will be treated with low-level laser therapy and patients in the control group will be treated with zero watt laser therapy in the same way. Therefore, the researcher is aware of the type of therapeutic intervention, but the participant and the person evaluating the information will not be aware of the two groups.
Placebo	Used
Assignment	Parallel
Other design features	

Secondary Ids	empty
Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics Committee of Isfahan University of Medical Sciences
Street address	Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City	Esfahan
Province	Isfahan
Postal code	8179964167
Approval date	2020-06-01, 1399/03/12
Ethics committee reference number	IR.MUI.MED.REC.1399.190
Health conditions studied	
1	
Description of health condition studied	Wrist ganglion cyst
ICD-10 code	M67.40
ICD-10 code description	Ganglion, unspecified site
Primary outcomes	
1	
Description	Pain score
Timepoint	Before, 4 and 8 weeks after the intervention
Method of measurement	Visual Analogue Scale (VAS)
Secondary outcomes	empty
Intervention groups	
1	
Description	Intervention group: All patients use a wristband. In the intervention group, patients receive laser by the "FLOWER" method as a point in the middle of the ganglion cyst with the intensity of 10 J and 4 points around it with the intensity of 5 J by a device with 0.5

watt power.
Category
Treatment - Other

2

Description

Control group: All patients use a wristband. In the control group, patients will be received a zero-watt laser in the same way as the intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Babak Vahdatpour

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Hezar Jarib Street, Isfahan.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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Vice Chancellor for Research, School of Medicine,
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Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Babak Vahdatpour

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

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Latest degree
Specialist
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City
Isfahan
Province

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available