Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Radial shockwave therapy in trigger finger treatment

Protocol summary

Study aim

Investigating the effect of radial shockwave therapy in the treatment of trigger finger

Design

The randomized clinical trial has a control group, the randomization method is performed in the form of restricted randomization and random allocation rule. The sample size in each group is 19 people.

Settings and conduct

The study population is the patients referred to the physical medicine and rehabilitation clinic of Firouzgar Hospital. In all patients outcome measures checked before treatment and after completing the 6-week treatment period and 3 months after the treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Patients with an age greater than or equal to 18 years and - Trigger finger grade two or three Exclusion criteria: - Patients who have been previously treated with Physiotherapy, corticosteroids and surgery - Patients with local infection, malignancy, rheumatoid arthritis, pregnancy and arrhythmia - Patients with musculoskeletal problems or nerve damage in the upper limb - Not using a splint during 6 weeks of treatment

Intervention groups

In one group of patients, it is prescribed for the treatment of trigger finger splint. The prescribed splint in these patients places the MCP joint in 15 degrees of flexion and the patient is taught to use it day and night (24 hours) for 6 weeks. During the treatment, in order to follow up the patients' use of the splint, the researcher calls them by phone. In the other group, patients are treated with radial shockwave in 6 sessions with one-week intervals. In this group, in addition to shockwave treatment, trigger finger splint is also prescribed for the patients, similar to the first group.

Main outcome variables

Frequency of triggering ،Severity of triggering ،Functional impact of triggering,Pain score,Disability of upper limb

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230405057829N1**
Registration date: **2023-04-18, 1402/01/29**
Registration timing: **prospective**

Last update: **2023-04-18, 1402/01/29**
Update count: **0**

Registration date

2023-04-18, 1402/01/29

Registrant information

Name

Simin Sajadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Radial shockwave therapy in trigger finger

treatment

Public title
Effect of Radial shockwave therapy in trigger finger treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients older than 18 years Patients with trigger finger grade two or three
Exclusion criteria:
Patients who have been previously treated with PT, corticosteroids and surgery Patients with local infection, malignancy, rheumatoid arthritis, pregnancy and arrhythmia Patients with musculoskeletal problems or nerve injury in the upper limb Not using a splint during 6 weeks of treatment
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method is performed as restricted randomization and random allocation rule. In this method, equal number of each group (according to the amount of sample size) are written on papers of the same size and design, numbers 1 and 2 (representing the first and second group) and inside non-transparent envelopes. that it is not possible to see inside the envelope) is placed and the sufferers are asked to choose one of them randomly after moving the envelopes.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Baharestan Square,Shafa hospital
City
Tehran
Province
Tehran
Postal code
1157637131
Approval date
2022-10-17, 1401/07/25
Ethics committee reference number
IR.IUMS.FMD.REC.1401.383

Health conditions studied

1

Description of health condition studied
Trigger Finger
ICD-10 code
M65.3
ICD-10 code description
Nodular tendinous disease

Primary outcomes

1

Description
The intensity of the patient's pain is based on scoring from one to ten
Timepoint
Before the treatment and after completing the 6-week treatment period and 3 months after the treatment
Method of measurement
How much the patient knows the intensity of his pain and gives a score to his current pain from 0 (no pain) to 10 (the most severe pain that a person can experience in his lifetime). We ask the patient to indicate his pain level on a special 10 cm ruler

2

Description
Frequency of triggering
Timepoint
Before the treatment and after completing the 6-week treatment period and 3 months after the treatment
Method of measurement
The patient gives a score from zero to ten on the number of times the trigger finger gets stuck. Zero is the least disorder and ten is the most severe condition.

3

Description
Functional impact of triggering
Timepoint
Before the treatment and after completing the 6-week treatment period and 3 months after the treatment
Method of measurement
The patient scores the dysfunction caused by trigger

finger from 0 to 10. 0 is the least disorder and 10 is the most severe

4

Description
Severity of triggering
Timepoint
Before the treatment and after completing the 6-week treatment period and 3 months after the treatment
Method of measurement
The patient scores the severity of the locking of the trigger finger from zero to ten. Zero is the least disorder and ten is the most severe condition

5

Description
Disability of upper limb
Timepoint
Before the treatment and after completing the 6-week treatment period and 3 months after the treatment
Method of measurement
Quick dash questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients are treated with radial shockwave in 6 sessions with one-week intervals, and the shockwave treatment protocol includes 1500 shocks, 2.5 bar energy and 15 Hz frequency. In this group, in addition to shockwave treatment for trigger finger patients A splint is also prescribed.
Category
Treatment - Devices

2

Description
Control group: In this group of patients, trigger finger splint is prescribed for treatment. The prescribed splint in these patients places the MCP joint in 15 degrees of flexion and the patient is taught to use it day and night (24 hours) for 6 weeks. During the treatment, in order to follow up the patients' use of the splint, the researcher calls them by phone
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Firuzgar hospital
Full name of responsible person
Maede Mollaei
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Firuzgar hospital,Behafarin street,valiasr square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hossein keivani
Street address
Hemat Highway next to Milad Tower, Iran University of Medical Sciences
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Phone
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Email
info@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Maede.Molaei
Position
Physical medicin and rehabilitation resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
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Latest degree
Medical doctor
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