

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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

Street address

Firuzgar hospital, Behafarin street, Valiasr square

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tehran

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Postal code

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Phone

+98 21 8214 1000

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maedemolaei415@gmail.com

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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+98 21 86701

Fax

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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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Maede Molaei

Position

physical medicin resident

Latest degree

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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