

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

The efficacy of shock wave therapy on improvement of clinical symptoms and function of patients with Dupuytren's contracture

Protocol summary

Study aim

The aim of this study is to determine the effect of shock wave therapy on improving the symptoms and function of patients with Dupuytren's Contracture.

Design

The present project is a self-control clinical trial that will be performed as a pilot study among 20 patients.

Settings and conduct

Referred patients to the Physical Medicine Clinics of Isfahan University of Medical Sciences, who have Dupuytren's Contracture, will be recruited into this study subjected to the inclusion and exclusion criteria. They will get 6 sessions of shock wave therapy once a week (with Storz Duolith SD1, Focus head, with 1.24 millie Jules per millie square meters energy, 2000 shocks and 3 Hz frequency per session). Visual Analogue Scale and Disabilities of the Arm, Shoulder and Hand questionnaire (DASH) and the angle of contracture will be measured before treatment and 6 and 14 weeks after the start of treatment. The data will be entered in SPSS version 25 and analyzed by appropriate descriptive and analytical statistical tests.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients who are equal or older than 18 years with clinical diagnosis of grade one or two Dupuytren's Contracture (mild or moderate severity) at least in one finger with written consent for participation in the study. However using physical or pharmaceutical modalities in the past 3 months; any chronic, neurological, or neuromuscular disorders affecting on hands; osteoporosis and contraindications to shock wave therapy (pregnancy and coagulation disorders) will be as exclusion criteria.

Intervention groups

In this study 6 sessions of shock wave therapy with intervals of once a week will be performed for 20 patients who already have Dupuytren's Contracture.

Main outcome variables

Severity of pain (VAS); functional status based on DASH

questionnaire; angle of contracture

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200607047676N1**

Registration date: **2020-07-04, 1399/04/14**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-04, 1399/04/14**

Update count: **0**

Registration date

2020-07-04, 1399/04/14

Registrant information

Name

Najmeh Salek

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3786 7599

Email address

n.salek@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-25, 1398/11/05

Expected recruitment end date

2021-01-24, 1399/11/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	National Ethics Committee of Isfahan University of Medical Sciences
Scientific title	Street address
The efficacy of shock wave therapy on improvement of clinical symptoms and function of patients with Dupuytren's contracture	Isfahan University of Medical Sciences, Hezar Jarib St.
Public title	City
Effect of shock wave in treatment of Dupuytren	Esfahan
Purpose	Province
Treatment	Isfahan
Inclusion/Exclusion criteria	Postal code
Inclusion criteria:	8174673461
Dupuytren's disorder with grade one or two (mild or moderate) Presence of disorder in at least one finger Patients older than or equal to 18 years Flexion contracture less than or equal to 15 degrees in the proximal interphalangeal joint (PIP) Flexion contracture less than or equal to 30 degrees in the metacarpophalangeal joint (MCP) Patient satisfaction with participating in the study after explaining the goals of the project to them	Approval date
Exclusion criteria:	2020-01-22, 1398/11/02
Pregnant patients or patients who intend to become pregnant during the study period Use of physical or pharmacological modalities in the last 3 months (physiotherapy treatments) The presence of any chronic, neurological, or neuromuscular disorders that affect the hands Osteoporosis Contraindications of shock wave (pregnancy and coagulation disorders)	Ethics committee reference number
Age	IR.MUI.MED.REC.1398.529
From 18 years old	
Gender	
Both	
Phase	
N/A	
Groups that have been masked	
No information	
Sample size	
Target sample size: 20	
Randomization (investigator's opinion)	
N/A	
Randomization description	
Blinding (investigator's opinion)	
Not blinded	
Blinding description	
Placebo	
Not used	
Assignment	
Single	
Other design features	
Secondary Ids	
empty	
Ethics committees	
1	
Ethics committee	
Name of ethics committee	

Health conditions studied

1

Description of health condition studied

Dupuytren's Contracture

ICD-10 code

M72.0

ICD-10 code description

Palmar fascial fibromatosis [Dupuytren]

Primary outcomes

1

Description

The severity of the pain

Timepoint

Before starting the intervention, 6 and 14 weeks after starting intervention

Method of measurement

Visual Analogue Scale

2

Description

Patients' functional status

Timepoint

Before starting the intervention, 6 and 14 weeks after starting intervention

Method of measurement

DASH questionnaire (Disabilities of the Arm, Shoulder and Hand)

3

Description

Contracture angle

Timepoint

Before starting the intervention, 6 and 14 weeks after starting intervention

Method of measurement

Goniometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For 20 patients, 6 shock wave sessions will be performed one week apart (one session per a week and the next session next week on the same day) on the nodule (with Storz Duolith SD1, Focus Head, energy: 1.24 mJ/mm² with a shock number of 2000 and a frequency of 3 Hz per session). Following the use of the gel, the probe will be placed perpendicular to the hand.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin Medical Center, Physical Medicine and Rehabilitation Unit

Full name of responsible person

Najmeh Salek

Street address

Sonbolestan Aly, Ebnesina Ave, Shohada Sq

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8148653141

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amin@mui.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Shaghayegh Haghjoo Javanmard

Street address

Hezar Jarib St., Isfahan University of Medical Science

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8174673461

Phone

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research@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Najmeh Salek

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact

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Position

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Other areas of specialty/work

Physical Medicine

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Person responsible for updating data

Contact

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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

No more information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

This study will publish information about the main outcomes and results of the study. There is currently no plan to disseminate other patient information even in an undetectable manner.

When the data will become available and for how long

After publishing the results

To whom data/document is available

No limit

Under which criteria data/document could be used

Citing the source

From where data/document is obtainable

Downloading the article from the journal's website or contacting the author of the article

What processes are involved for a request to access data/document

Downloading the article from the journal's website or contacting the author of the article

Comments