Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 milie 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 questionare; 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

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

Public title
Effect of shock wave in treatment of Dupuytren
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
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
Exclusion criteria:
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)
Age
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
National Ethics Committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jarib St.
City
Esfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-01-22, 1398/11/02
Ethics committee reference number
IR.MUI.MED.REC.1398.529

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

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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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No. 3, Mehr Building, 66 Aly, Bagh daryacheh St

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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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