

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

### 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

Isfahan

#### 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/mm<sup>2</sup> 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

#### City

Esfahan

#### Province

Isfahan

#### Postal code

8148653141

#### Phone

+98 31 3445 5051

#### Email

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

#### City

Esfahan

#### Province

Isfahan

#### Postal code

8174673461

#### Phone

+98 31 3668 8138

#### Email

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

#### Street address

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

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8186756798

#### Phone

+98 31 3786 7599

#### Email

n.salek@resident.mui.ac.ir

## Person responsible for scientific 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

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Esfahan University of Medical Sciences

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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