

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Efficacy assessment of Extracorporeal ShockWave Therapy (ESWT) in treatment of Trigger finger patients

#### Protocol summary

##### Study aim

The goal is to find an effective and non invasive method for Trigger finger treatment, particularly for patients with non responsive or reoccurring despite the other ones treatments methods and patients with Diabetes Mellitus.

##### Design

This study consist of 19 trigger finger patients referred to Esfahan University of Medical Science's clinics who are suffering from inclusion criteria.

##### Settings and conduct

Every patient is treated by ESWT for 3 weeks (1 week interval between sessions). Radial head protocol includes 1000 shock, at an energy flux density of 2 bar, with the frequency of 15 Hz. Focus protocol includes 500 shock, at an energy flux density of 0.1 bar, with the frequency of 4 Hz. Focus head will be used directly on nodule and maximum tenderness while radial head will employed on surrounding soft tissues.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria consists of Trigger finger, grade 1 or more. Exclusion criteria consists of Previous treatment in less than last 6 months, including corticosteroid injection or surgical release, Bleeding disorders, Pregnancy, Malignancy, Local infection, Arrhythmia and cardiac pace maker.

##### Intervention groups

This study consist of 19 trigger finger patients. Every patient will be treated by Extra Corporal Shock Wave Therapy for 3 weeks (1 week interval between sessions). No control group will be employed, as well as any other groups.

##### Main outcome variables

1.Pain intensity: due to Visual Analogue Scale. 2.Trigger finger grading: due to Quinnell trigger finger score. 3.Dysfunction: due to quick DASH(Disability of Arm, Shoulder and Hand) system.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170915036191N2**

Registration date: **2018-02-08, 1396/11/19**

Registration timing: **prospective**

Last update: **2018-02-08, 1396/11/19**

Update count: **0**

##### Registration date

2018-02-08, 1396/11/19

##### Registrant information

##### Name

**Name of organization / entity**

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3771 8986

##### Email address

f.momeni@resident.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-09, 1396/11/20

##### Expected recruitment end date

2018-03-01, 1396/12/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy assessment of Extracorporeal ShockWave

Therapy (ESWT) in treatment of Trigger finger patients

## Public title

"Shock Wave in Trigger finger"

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Trigger finger, grade 1 or more

### Exclusion criteria:

Previous treatment in less than last 6 months, including corticosteroid injection or surgical release Bleeding disorders Pregnancy Malignancy Local infection Arrhythmia and cardiac pace maker

## Age

From **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **19**

Actual sample size reached: **19**

## 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

Ethics committee of Esfahan University of Medical Sciences

##### Street address

Esfahan University of Medical Sciences, Hezar Jirib Ave

##### City

Esfahan

##### Province

Isfahan

##### Postal code

کد پستی: ۸۱۷۴۶-۷۳۴۶۱

#### Approval date

2016-09-28, 1395/07/07

#### Ethics committee reference number

IR.MUI.REC.1395.3.593

## Health conditions studied

### 1

#### Description of health condition studied

Trigger finger

#### ICD-10 code

M65.30

#### ICD-10 code description

Trigger finger, unspecified finger

## Primary outcomes

### 1

#### Description

Pain intensity due to Visual Analogue Scale (0-10)

#### Timepoint

Pain intensity due to Visual Analogue Scale system, before, immediately after, 6 weeks and 18 weeks after treatment.

#### Method of measurement

Visual Analogue Scale (0-10)

### 2

#### Description

Trigger finger grading: due to Quinnell Trigger finger score

#### Timepoint

Before, immediately after, 6 weeks and 18 weeks after treatment.

#### Method of measurement

Quinnell Trigger finger score

### 3

#### Description

Dysfunction: due to Quick Disability of Arm, Shoulder and Hand System

#### Timepoint

Before, immediately after, 6 weeks and 18 weeks after treatment.

#### Method of measurement

Quick Disability of Arm, Shoulder and Hand System

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Target group consists of 19 Trigger finger patients. Every patient will be treated by Extra Corporal Shock Wave Therapy for 3 weeks (1 week interval between sessions). Radial head protocol includes 1000 impulses, at an energy flux density of 2 bar, with the frequency of 15 Hz. Focus protocol includes 500 impulses, at an energy flux density of 0.1 bar, with the frequency of 4 Hz. Focus

head will be used directly on nodule and maximum tenderness, while radial head will employed on surrounding soft tissues.

**Category**

Treatment - Devices

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Ayatollah Kashani hospital

**Full name of responsible person**

Fahime Momeni

**Street address**

Ayatollah Kashani hospital, South Kashani Ave

**City**

Esfahan

**Province**

Isfahan

**Postal code**

۸۳۴۳۴-۸۱۸۳۹

**Phone**

+98 31 3233 0091

**Email**

f.momeni@resident.mui.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ahmad Movahedian Attar

**Street address**

No4 building, Esfahan University of Medical Sciences,  
Hezar Jirib Ave

**City**

Esfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Phone**

+98 31 3668 8138

**Fax**

**Email**

research@mui.ac.ir

**Web page address**

http://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**

Fahime Momeni

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

Physical Medicine and Rehabilitation Department,  
Alzahra Hospital, Shohadaye Sofe Ave

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3670 0666

**Email**

f.momeni@resident.mui.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

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8174675731

**Phone**

+98 31 3670 0666

**Email**

f.momeni@resident.mui.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

**Title and more details about the data/document**

All of data, after unrecognizable process are accessible.

**When the data will become available and for how long**

Access is possible 1 year after publish.

**To whom data/document is available**

Access is possible just for academic research centers.

**Under which criteria data/document could be used**

Data Analysis is allowed and there is not any specific limitation.

**From where data/document is obtainable**

Requests should be send to electronic mail and attach documented mail from associated research center.

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

After request receiving, inquiry mail will be send for associated research center. After confirmation, data will be send for applicant.

**Comments**