

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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 updating data**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

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