Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Efficacy assessment of Extracorporal 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 reoccuring 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 Extracorporal 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
Isfehan
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

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Esfahan

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+98 31 3233 0091

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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

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Fax

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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

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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

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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