

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Efficacy assessment of ESWT in treatment of de Quervain's Tenosynovitis for patients

Protocol summary

Study aim

to assess the efficacy of extracorporeal shockwave therapy in the treatment of patients with de Quervain's tenosynovitis in the present study

Design

controlled, randomized, clinical trial study

Settings and conduct

patients with de Quervain's Tenosynovitis who referred to Physical medicine and rehabilitation centers of Isfahan University of Medical Sciences during 2015-2018:
Intervention group: shock wave therapy control group: Placebo

Participants/Inclusion and exclusion criteria

The inclusion criteria were patients with de Quervain's Tenosynovitis, with age over 18 years, no history using of physiotherapy modalities or corticosterone injections for disease during a recent month and written informed consent for participation in the study. De Quervain's Tenosynovitis was diagnosed based on standard criteria including pain and tenderness in the lateral wrist and positive result of the Finkelstein test. However, in case of other neurological disorders and rheumatologic diseases causing wrist pain, pregnancy, history of fracture or surgery in the hand or severe trauma and coagulation disorders, were excluded from the study. Also, the patients who had chosen to withdraw the study during treatment or had a severe or acute complication after intervention or need to change the treatment were excluded from the study

Intervention groups

the patients were randomly divided into two parallel groups as extracorporeal shock wave therapy and placebo based on Random Allocation Software

Main outcome variables

Average duration of disease; evaluation of wrist pain; evaluation of disability in arm, shoulder and hand

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120729010439N2**

Registration date: **2019-06-17, 1398/03/27**

Registration timing: **retrospective**

Last update: **2019-06-17, 1398/03/27**

Update count: **0**

Registration date

2019-06-17, 1398/03/27

Registrant information

Name

Babak Vahdatpour

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 5555

Email address

vahdatpour@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

2016-05-21, 1395/03/01

Actual recruitment end date

2018-05-22, 1397/03/01

Trial completion date

2018-05-22, 1397/03/01

Scientific title

Efficacy assessment of ESWT in treatment of de Quervain's Tenosynovitis for patients

Public title

Effect of extracorporeal shockwave therapy in the patients with de Quervain tenosynovitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with de Quervain's Tenosynovitis . De Quervain's Tenosynovitis was diagnosed based on standard criteria including pain and tenderness in the lateral wrist and positive result of the Finkelstein test no history using of physiotherapy modalities or corticosterone injections for disease during a recent month written informed consent for participation in the study

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **26**

Actual sample size reached: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

After filling written informed consent, patients randomly divided into placebo or treatment group by randomizer software.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Soffeh street

City

Isfahan

Province

Isfahan

Postal code

8174673441

Approval date

2016-11-21, 1395/09/01

Ethics committee reference number

IR.Mui.Rec.1395.3.805

Health conditions studied

1

Description of health condition studied

Quervain's Tenosynovitis

ICD-10 code

M65.4

ICD-10 code description

Radial styloid tenosynovitis [de Quervain]

Primary outcomes

1

Description

DISABILITIES OF THE ARM, SHOULDER AND HAND)DASH

Timepoint

in the beginning and the weeks 3 and 6 after onset treatment

Method of measurement

questioner

Secondary outcomes

1

Description

evaluation of wrist pain

Timepoint

in the beginning and the weeks 3 and 6 after onset of treatment

Method of measurement

VAS

Intervention groups

1

Description

Intervention group: shock wave therapy

Category

Treatment - Other

2

Description

Control group: therapy with turned on machine without shock induction

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

kashani educational medical center

Full name of responsible person

Elham Ataei

Street address

Kashani street

City

Isfahan

Province

Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoo

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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

Babak Vahdatpour

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

After making sure that the participants personal data is not possible to track, all the data and outcomes can be shared

When the data will become available and for how long

5 years after publishing the data

To whom data/document is available

Verified university research centers

Under which criteria data/document could be used

research and therapeutic purposes

From where data/document is obtainable

sending e-mail to the corresponding person

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

receiving e-mail and checking the inquiry with the related university. After confirmation they will be introduced to our center to receive the data.

Comments