

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The effects of focused shock wave on pain, range of motion, muscle strength and quality of life in non-professional athletes with chronic supraspinatus tendinopathy.

#### Protocol summary

##### Study aim

Effects of focused shock wave on pain, range of motion, muscle strength and quality of life in non-professional athletes with chronic supraspinatus tendinopathy

##### Design

Randomized clinical trial, without control group, on 32 participants, using block randomization

##### Settings and conduct

This is a two-blinded block randomized clinical trial that compares the effects of shock wave and friction massage on supraspinatus tendinopathy. Evaluation and treatment of cases is done by another physiotherapist in the Physiotherapy Clinic of Oxin. The variables and measurement method and treatment protocol in the groups are as follows: Range of flexion, abduction, external rotation with an inclinometer, strength of the supraspinatus with a dynamometer, and pressure pain threshold of the supraspinatus, middle deltoid, and upper trapezius with an algometer. Determination of visual pain using questionnaire before and after each treatment session and quality of life with questionnaire. Treatment protocol for group 1 performing 4 shock wave sessions and for group 2 performing 4 sessions friction massage once a week. Both groups also receive 12 training sessions (3 times a week).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: non-professional athletes; pain in sport activities in last 3 months; age limitation 20-45 years old; body mass index below 30; being positive at least 2 of these tests: empty can, painful arc, Hawkins. Exclusion criteria: all contraindications for shock wave; history of surgery, fracture or osteoarthritis in the treatment areas.

##### Intervention groups

Intervention group 1: 4 shock wave sessions once a week  
Intervention group 2: 4 friction massage sessions once a week  
Both groups receive 12 sessions of exercise therapy (3 times a week)

#### Main outcome variables

Pain reduction, improve range of motion and quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220829055825N1**

Registration date: **2023-01-01, 1401/10/11**

Registration timing: **prospective**

Last update: **2023-01-01, 1401/10/11**

Update count: **0**

##### Registration date

2023-01-01, 1401/10/11

##### Registrant information

##### Name

Alireza Karimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2676 7708

##### Email address

karimi.ar@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-21, 1401/11/01

##### Expected recruitment end date

2023-04-19, 1402/01/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of focused shock wave on pain, range of motion, muscle strength and quality of life in non-professional athletes with chronic supraspinatus tendinopathy.

**Public title**

Effect of focused shock wave on chronic supraspinatus tendinopathy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Non-professional athletes ( 2 to 3 hours per week) Pain in sport activities in last 3 month Age limitation 20-45 years old Body mass index below 30 Being positive at least 2 of these test: empty can, painful arc, Hawkins

**Exclusion criteria:**

All contraindication of shock wave History of surgery, fracture or osteoarthritis in the treatment areas

**Age**

From **20 years** old to **45 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Investigator
- Data analyser

**Sample size**

Target sample size: **32**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

AABB; BBAA; ABAB; BABA; ABBA; BAAB. Write these items on six paper and put in the six packets. Draw eight times until eight envelopes are selected, provided that the envelopes are repeated; each characteristics of the specification of the four allocations of the individual.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The main researcher in this study won't aware of the randomization of the patients and the patients will treat by another therapist who will aware of the treatment groups. At the end, the data analyst will analyze the data without knowing what treatment package groups 1 and 2 received.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethic Committee of Iran University of Medical Sciences

**Street address**

Next to Milad Tower, Hemat Highway, Iran University of Medical Sciences.

**City**

Tehran

**Province**

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**Postal code**

1449614535

**Approval date**

2022-07-28, 1401/05/06

**Ethics committee reference number**

IR.IUMS.REC.1401.446

**Health conditions studied****1****Description of health condition studied**

Chronic supraspinatus tendinopathy

**ICD-10 code**

M75.80

**ICD-10 code description**

Other shoulder lesions, unspecified shoulder

**Primary outcomes****1****Description**

Range of motion of flexion, abduction, external rotation of the shoulder

**Timepoint**

At the first and end of treatment program

**Method of measurement**

Range of motion with inclinometer

**2****Description**

Strength of the supraspinatus muscle

**Timepoint**

At the first and end of treatment program

**Method of measurement**

Muscle strength with dynamometer

**3****Description**

Pain pressure threshold of the muscles of the

supraspinatus, middle deltoid, and upper trapezius.

**Timepoint**

At the first and end of treatment program

**Method of measurement**

Pain pressure threshold with algometer

**4****Description**

Amount of Visual Analog Scale

**Timepoint**

Before and after each session

**Method of measurement**

Visual Analog Scale (VAS) questionnaire

**5****Description**

Quality of life

**Timepoint**

At the first and end of treatment program

**Method of measurement**

SF-36 questionner

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group:4 session ( one session per week)  
Extracorporeal Shockwave Therapy(ESWT) Focused Storz  
( Swiss 2019) . Protocol: 1000-2000 plus, frequency 4 Hz,  
intensity 0.1 mj/mm2

**Category**

Rehabilitation

**2****Description**

Control group:4 session ( one session per week) Friction  
massage for 10 minutes on supraspinatus tendon,  
myofascial tissue of supraspinatus, deltoid and upper  
trapezius.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Oxin Physio clinic

**Full name of responsible person**

Alireza Karimiahmadabadi

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No 11/9., Fakharmoghamad Ave., Dadman Blvd.,  
Sanat Squ.

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Ghorban Taghizadeh

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Physical Therapy Dept., 3rd floor, School of  
rehabilitation Sciences, Madadkaran Ave., Shah  
Nazari St., Maadar Sq., Mirdamaad Blv., Tehran, Iran

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taghizadeh.gh@yahoo.com

**Web page address**

<https://en.iuims.ac.ir/>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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**

Oxin physiotherapy Clinic

**Full name of responsible person**

Alireza Karimiahmadabadi

**Position**

Master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Soheil\_Mansour Sohani

**Position**

Associate professor of physiotherapy

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

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**Full name of responsible person**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Sharing plan

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

Undecided - It is not yet known if there will be 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