

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Clinical Trial to comparison the effectiveness of Extra Corporal Shock Wave Therapy and other conventional physiotherapy interventions on the amount of knee pain in patients With Moderate knee Osteoarthritis

#### Protocol summary

##### Summary

This study aimed to compare the effectiveness of shock wave therapy with other conventional physiotherapy interventions on the amount of pain in patients with Moderate Knee Osteoarthritis referred to Shohada Hospital of Tabriz. In this study 120 patients at the age of 50-70 years old with Moderate Knee Osteoarthritis, diagnosed based on clinical and radiological examinations, will participate. Patients with rheumatic disease, cardiac conduction block, epilepsy, deep vein thrombosis, pregnancy, and any contraindication for modalities, and patients who had past medical history of surgery, fractures, injections and wound at the knee joint region will be excluded. Patients will be selected randomly using sealed envelope and assigned into 3 groups including control, intervention 1 and intervention 2 groups .At first, VAS scale, WOMAC questionnaire and TUG test will be filled out for all patients and knee joint range of motion and HSCRp blood level will be evaluated for them. Control group will receive just exercise program. Intervention 1 group will receive shock wave therapy for 5 sections during 3 weeks with moderate energy plus the exercise programs as well as control group. Intervention 2 group will receive conventional physiotherapy such as Hot Pack and TENS and Ultra Sound for ten sections in addition to the exercise programs as well as control group. Strengthening exercise for the Quadriceps muscles, isometric exercise with or without weight, and weight bearing exercise inside and outside of water will be done for all patients. Life style modification education will be done for all patients. The amount of pain as primary out come and range of motion and knees function and level of HSCRp as secondary out comes will be assessed. All above variables will be reevaluated after 3 and 7 weeks.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201608044641N12**  
Registration date: **2017-02-06, 1395/11/18**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-06, 1395/11/18

##### Registrant information

##### Name

Bina Eftekharsadat

##### Name of organization / entity

Tabriz university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1330 3193

##### Email address

binasadat@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for Research of Tabriz University of Medical Sciences; Research Center of Tabriz Physical Medicine and Rehabilitation.

##### Expected recruitment start date

2016-10-22, 1395/08/01

##### Expected recruitment end date

2017-03-19, 1395/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Clinical Trial to comparison the effectiveness of Extra Corporal Shock Wave Therapy and other conventional physiotherapy interventions on the amount of knee pain in patients With Moderate knee Osteoarthritis

**Public title**  
Effectiveness of Extra corporal Shock Wave therapy in the treatment of Knee Arthritis

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
Inclusion criteria: patients with moderate knee osteoarthritis grade 2 and 3, based on Kellgren & Lawrence scale; patients at the age of 50-70 years. Exclusion criteria: patients with rheumatologic disorders such as rheumatoid arthritis; past medical history of surgery on knee joints; past medical history of fracture in lower limbs with involvement of articular surface of knees; mild and severe knee osteoarthritis ( 1 and 4 radiological scale); patients with electrical implants such as pace makers; past medical history of conduction block cardiac disease; patients with epileptic disorders; patients with pregnancy; patients with deep vein thrombosis; past medical history of intra-articular injections since 6 months ago and systemic corticosteroid drugs consumption since 1 month ago; patients with balance disturbance; patients with neuropathy and sensory impairments; existence of any skin lesions around the knee joints; BMI above 30; patients who are unable to complete the questionnaire and procedures.

**Age**  
From **50 years** old to **70 years** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **120**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
**Placebo**

Not used  
**Assignment**  
Parallel

**Other design features**

**Secondary IDs**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Central building number2 (third floor), Tabriz University of Medical Sciences, Golgasgt street,Tabriz.

##### City

Tabriz

##### Postal code

5166614756

##### Approval date

2016-07-04, 1395/04/14

##### Ethics committee reference number

IR.TBZMED.REC.1395.288

## Health conditions studied

### 1

#### Description of health condition studied

Moderate knee osteoarthritis

#### ICD-10 code

M17

#### ICD-10 code description

Gonarthrosis [arthrosis of knee]

## Primary outcomes

### 1

#### Description

The amount of Pain

#### Timepoint

Time zero(baseline), 3weeks later,7 weeks later.

#### Method of measurement

Visual Analog Scale

## Secondary outcomes

### 1

#### Description

Knee range of motion

#### Timepoint

Time zero (baseline),3weeks later,7 weeks later.

#### Method of measurement

Goniometer.

### 2

#### Description

knee function

#### Timepoint

Time zero (baseline),3weeks later,7 weeks later.

#### Method of measurement

WOMAC questionnaire

### 3

#### **Description**

HSCR level

#### **Timepoint**

Time zero (baseline), final evaluation at week 7.

#### **Method of measurement**

laboratory kit

## **Intervention groups**

### 1

#### **Description**

The control group will receive just exercise programs. Exercise program consists of strengthening exercise for quadriceps muscle, Isometric exercise with and without weight, weight bearing exercise inside and outside the water.

#### **Category**

Other

### 2

#### **Description**

Intervention group 1: The patients will receive Shock Wave Therapy for the affected knee at the site with maximum pain amount in sitting position, flexion of knee joint and abduction and external rotation of hip joint, during 3 weeks; 2000 shock/session; 5 session; energy level 2-4; pulse rate 160/min; 6-10 Hz; density 0.18 mj/mm<sup>2</sup>; with zimmer shokwave device, made in Germany

#### **Category**

Other

### 3

#### **Description**

Group intervention 2: The patients will receive conventional physiotherapy interventions for 10 sessions which is consisted of 1) Hot Pack at 74.5 degrees centigrade for 20 minutes, at the knee region with maximum pain; and 2) TENS: pulse duration 20-100 Microsecond; 50% duty cycle; continuous amplitude at the maximum pain region of affected knee; frequency < 200pps, and 3) Ultra Sound: 1MHz Frequency; intensity of 2.5 W/cm<sup>2</sup>; pulse at duty cycle of 25%; for 10 minute.

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shohada hospital, Tabriz University of Medical Scienc

##### **Full name of responsible person**

Razieh ahmadi

##### **Street address**

Shohada Hospital( Physical medicine and

rehabilitation ward), Golshahr street, Tabriz.

##### **City**

Tabriz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Physical Medicine and Rehabilitation Research Center of Tabriz

##### **Full name of responsible person**

Dr Seyed Kazem Shakori, MD

##### **Street address**

Eemam Reza Hospital(Physical Medicine and Rehabilitation, Research Center), Golgasht street, Tabriz.

##### **City**

Tabriz

##### **Grant name**

--

##### **Grant code / Reference number**

--

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Physical Medicine and Rehabilitation Research Center of Tabriz

##### **Proportion provided by this source**

100

##### **Public or private sector**

*empty*

##### **Domestic or foreign origin**

*empty*

##### **Category of foreign source of funding**

*empty*

##### **Country of origin**

##### **Type of organization providing the funding**

*empty*

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Tabriz University of Medical Science

##### **Full name of responsible person**

Dr Razieh Ahmadi

##### **Position**

Resident in training

##### **Other areas of specialty/work**

##### **Street address**

Emam Reza Hospital, Golgasht street, Tabriz .

##### **City**

Tabriz

##### **Postal code**

5166614756

##### **Phone**

+98 41 3337 3967

##### **Fax**

##### **Email**

ahmadi.dr62@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Bina Eftekhari Sadat

**Position**

Associate Professor.

**Other areas of specialty/work**

**Street address**

Emam Reza Hospital, Golgasht street, Tabriz.

**City**

Tabriz

**Postal code**

5166614756

**Phone**

+98 41 3337 3967

**Fax**

**Email**

binasadat@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Science

**Full name of responsible person**

Dr Razieh Ahmadi

**Position**

Clinical Assistant

**Other areas of specialty/work**

**Street address**

Emam Reza Hospital, Golgasht street, Tabriz.

**City**

Tabriz

**Postal code**

5166614756

**Phone**

+98 41 3337 3967

**Fax**

**Email**

ahmadi.dr62@gmail.com

**Web page address**

## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*