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)

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+98 41 1330 3193

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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 kellegren &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 sever 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 month 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 comittee 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 motin

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
HSCRP level
Timepoint
Time zero (baseline),final evaluation at week 7.
Method of measurement
laberatory 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/mm2; 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/cm2; 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
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Person responsible for scientific inquiries

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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