

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effects of electrical dry needling in addition to routine physiotherapy on pain, range of motion and functional disability in patients with moderate knee osteoarthritis

Protocol summary

Study aim

To compare the effects of electrical dry needling in addition to routine physiotherapy on pain, range of motion, and functional disability in patients with moderate knee osteoarthritis.

Design

Randomized clinical Trial. single-blinded, 92 samples, parallel groups, randomized by computer-generated method and further concealed envelope method used for allocation in the group. In the envelope, 1 will be code for the control group and 2 will be code for the experimental group.

Settings and conduct

The study will be conducted by Physical Therapy Department of the UNIVERSITY OF LAHORE Teaching Hospital, Lahore

Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Age group 30-60 years. • Both male and female. • Patients with degenerated osteoarthritis. • Unilaterally, most painful knee will be treated. • Moderate osteoarthritis, Grade II and III. • Radiologically diagnosed knee osteoarthritis. • Chronic knee pain for more than three months. • Less than half an hour of morning stiffness. Exclusion Criteria: • Any previous trauma, fracture, subluxation, dislocation, surgery, or bony abnormalities around the knee joint in the past six months. • Cancer • Suppression of the immune system • Pregnancy • Recent infection • Any dermatological issues • Unexplained weight loss/gain • Dysfunction of bladder

Intervention groups

Group (A) Initially, routine physical therapy exercises will be performed including hot pack for 10 minutes of duration, manual therapy including passive mobilization of knee joint, strengthening exercises & muscle stretching. Group (B) participants will receive Electrical Dry Needling with routine physical therapy exercises.

Electrical Dry Needling for 10 minutes at frequency of 2 Hz, width of 100us and continuous biphasic waveform through 2 diagonal channels of 4 needles for 3 times a week.

Main outcome variables

Pain, Range of motion and functional disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210321050752N5**

Registration date: **2023-12-19, 1402/09/28**

Registration timing: **retrospective**

Last update: **2023-12-19, 1402/09/28**

Update count: **0**

Registration date

2023-12-19, 1402/09/28

Registrant information

Name

Muhammad Waqas

Name of organization / entity

The University of Lahore

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-17, 1401/10/27

Expected recruitment end date

2023-12-17, 1402/09/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of electrical dry needling in addition to routine physiotherapy on pain, range of motion and functional disability in patients with moderate knee osteoarthritis

Public title

Effects of electrical dry needling in addition to routine physiotherapy on pain, range of motion and functional disability in patients with moderate knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age group 30-60 years. Patients with degenerated osteoarthritis. Unilaterally, most painful knee will be treated. Moderate osteoarthritis, Grade II and III. Radiologically diagnosed knee osteoarthritis. Chronic knee pain for a duration of more than three months. Less than half hour of morning stiffness.

Exclusion criteria:

Any previous trauma, fracture, subluxation, dislocation, surgery or bony abnormalities around knee joint in the past 6 months. Cancer or Suppression of immune system. Any neurological deficits in lower extremity. Pregnancy. Any dermatological issues. Unexplained weight loss/gain. Dysfunction of bladder OR Recent infection

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

The lottery method will be used for randomization by using random numbers and further concealed envelop method will be used for allocation in the group. In the envelop, 1 will be code for the control group and 2 will be code for the experimental group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Assessor will only assess the patient at baseline and after follow-up for treatment outcomes. Assessor safe the data for follow-up and will not share it with any therapist or patient. At any stage, the assessor is

unaware of the treatment and control group. The study was single-blinded. The assessor was unaware of the treatment given to either groups 1 or 2.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

The University of Lahore

Street address

Raiwind Road Campus: 1-Km, Raiwind Road, Near Thokar Niaz Big, Lahore

City

Lahore

Postal code

5400

Approval date

2023-01-17, 1401/10/27

Ethics committee reference number

REC-UOL-301-01-2023

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

Pain

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

2**Description of health condition studied**

Functional disability

ICD-10 code

Z73.6

ICD-10 code description

Limitation of activities due to disability

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

Pain

Timepoint

Pain, range of motion and functional disability will be assess at baseline, week 4 and follow up after 2 months.

Method of measurement

2

Description

Functional disability

Timepoint

Pain, range of motion and functional disability will be assess at baseline, week 4 and follow up after 2 months.

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group (B) participants will receive Electrical Dry Needling with routine physical therapy exercises. Initially Routine physical therapy exercises will be performed including hot pack for 10 minutes of duration, manual therapy including passive mobilization of knee joint and muscle stretching. Then exercises like riding a stationary bicycle, range of motion exercises and strengthening exercises of the lower limbs with the hold of 5-10 seconds with 10 repetitions and 3 sets each. Group B participants will have Electrical Dry Needling for 10 minutes at frequency of 2 Hz , width of 100us and continuous biphasic waveform through 2 diagonal channels of 4 needles for 3 times a week along with routine physical therapy exercises. The electrical stimulation would be applied on the most painful knee of the patients in 3 sessions in a week.

Category

Rehabilitation

2

Description

Control group: Group (A) participants will receive routine physical therapy exercises. Initially routine physical therapy exercises will be performed including hot pack for 10 minutes of duration, manual therapy including passive mobilization of knee joint and muscle stretching. Then exercises like riding a stationary bicycle, range of motion exercises and strengthening exercises of the lower limbs with the hold of 5-10 seconds with 10 repetitions and 3 sets each. Each session will last for 30 minutes with 12 sessions on alternate days (3 sessions / week) will be given.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical Therapy Department of UNIVERSITY OF LAHORE Teaching Hospital, Lahore

Full name of responsible person

Dr. Asim Arif

Street address

Raiwind Road Campus: 1-Km, Raiwind Road, Near Thokar Niaz Big, Lahore

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Self Supported

Full name of responsible person

Hamail Chatha

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Grant name

Grant code / Reference number

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

No

Title of funding source

Self Supported

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

The University of Lahore

Full name of responsible person

Muhammad Waqas

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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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

Yes - There is 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

Pain and functional disability status

When the data will become available and for how long

6 months after publication.

To whom data/document is available

Academic and clinical research writers.

Under which criteria data/document could be used

Never without permission.

From where data/document is obtainable

From Muhammad Waqas through mail id. drwaqasfayyaz@gmail.com or through a Researchgate account.

https://www.researchgate.net/profile/Muhammad-Waqas-26?ev=hdr_xprf

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

From Muhammad Waqas through mail id. drwaqasfayyaz@gmail.com or through a Researchgate account.

https://www.researchgate.net/profile/Muhammad-Waqas-26?ev=hdr_xprf

Comments