

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effects of Routine physical therapy with and without Hydrotherapy on Pain Intensity and Functional activity in knee Osteoarthritis Patients.

Protocol summary

Study aim

Aim of study was to know the effects of routine physical therapy with and without hydrotherapy on pain intensity and functional activity in knee osteoarthritis patients.

Design

A concealed, randomized, single blind clinical trial with parallel group design, consisted of 58 cases, enrolled between 26 December 2019 and 25 August 2020.

Settings and conduct

Data was collected from Department of Physical therapy university of Lahore teaching hospital Lahore Pakistan. Single blind study and assessor was blind in it.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Both males and females; 40 to 65 years of the age; Patients with osteoarthritis clinically diagnosed by orthopedic surgeon; Grade 2 and Grade 3 osteoarthritis patient; Have been diagnosed with at least unilateral degenerated OA. Non inclusion criteria: Hydrophobia; Traumatic OA; Recent surgery; Any cardiac disease; Fracture of lower limb; Knee joint replacement

Intervention groups

Control group: They received the regular designed physical therapy in which include TENS, HOT PACK, and Strengthening of knee joint. Intervention group : They received both routine physical therapy and hydrotherapy In routine PT, TENS, hot pack and strengthening of knee joint was given. In hydro three stages was included, warm-up (5 min), strengthening exercises (20 min), and a cool-down session (5 min). One set of 10 repetitions was increased to three sets of 10 repetitions for each exercises. Ankle weight was used around the ankle to provide additional resistance

Main outcome variables

Functional activity; pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200827048538N1**

Registration date: **2020-10-02, 1399/07/11**

Registration timing: **retrospective**

Last update: **2020-10-02, 1399/07/11**

Update count: **0**

Registration date

2020-10-02, 1399/07/11

Registrant information

Name

Sofia Tariq

Name of organization / entity

University of Lahore

Country

Pakistan

Phone

+92 42 36849457

Email address

sofiatariq32@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-26, 1398/10/05

Expected recruitment end date

2020-05-26, 1399/03/06

Actual recruitment start date

2019-12-26, 1398/10/05

Actual recruitment end date

2020-08-25, 1399/06/04

Trial completion date

2020-08-25, 1399/06/04

Scientific title

Effects of Routine physical therapy with and without Hydrotherapy on Pain Intensity and Functional activity in knee Osteoarthritis Patients.

Public title

Effects of Routine physical therapy with and without Hydrotherapy in knee Osteoarthritis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Both males and females 40 to 65 years of the age
Patients with osteoarthritis (OA) clinically diagnosed by orthopedic surgeon Grade 2 and Grade 3 osteoarthritis
Have been diagnosed with at least unilateral degenerated OA

Exclusion criteria:

Hydrophobia Traumatic OA Recent surgery Any cardiac disease Neurological disorders Fracture of lower limb Knee joint replacement Skin diseases of lower limb Structural and functional disability Pathological and systematic disease Not to be used any walking support (such as walking stick or crutches)

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **58**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done by using lottery method. Non-Probability Convenient Sampling was used to recruit the individuals for the study and then randomization was done by lottery method to divide the individuals into 2 groups. Sealed envelope will be used for allocation concealment.

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessor was blind and unaware of the treatment given into both control and study groups. Assessor was take 1st week and 4th week of followup total scoring.

Placebo

Not used

Assignment

Parallel

Other design features

Null

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University Institute of Physical Therapy

Street address

House no.23; D/1 street; no.41 new colony
Mujahidabad; Sahuwari

City

Lahore

Postal code

54000

Approval date

2019-12-26, 1398/10/05

Ethics committee reference number

IRB-UOL-FAHS/683/2020

Health conditions studied

1

Description of health condition studied

Grade 2 and Grade 3 Knee Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Functional activity

Timepoint

Pre-assessment was taken at 1st week and final assessment was taken after 4 weeks.

Method of measurement

Functional activity was measured by WOMAC Scale.

2

Description

Pain intensity

Timepoint

Pre-assessment was taken at 1st week and final assessment was taken after 4 weeks.

Method of measurement

Pain assessment was measured by VAS Scale.

Secondary outcomes

empty

Intervention groups

1

Description

Control Group: In regular physical therapy treatment include TENS, hot pack and isometrics of knee joint. Treatment period for almost 40 minutes. Total 12

sessions were given to patients, 3 times per week for consecutive 4 weeks.

Category

Rehabilitation

2

Description

Intervention group: In which both routine physical therapy and hydrotherapy treatment include . In hydrotherapy each session were include the following components: warm-up, lower limb ROM exercises and strengthening exercises. The program was including into three stages: warm-up (5 min), strengthening exercises (30 min), and a cool-down session (5 min). Warm-up exercises consisted of walking in the water and increasing velocity followed by stretching exercises of the anterior and posterior muscles of the lower limbs. After the warm-up session, participants will be performed lower limb strengthening exercises. In strengthening exercises Single leg squad, Semi squad, Side walk include. The cool-down session consisted of light walking. Participants will be instructed to perform the exercises on the high possible intensity. Ankle weight will be used around the ankle to provide additional resistance. Treatment period for almost one hour. Total 12 sessions were given to patients, 3 times per week for consecutive 4 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical therapy department, University Teaching Hospital, Lahore.

Full name of responsible person

Sofia Tariq

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Lahore

Full name of responsible person

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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

Null

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

University of Lahore

Full name of responsible person

Sofia tariq

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there is no further decision and information decided yet.

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