Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 trail 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
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Pakistan
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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
Nill

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

Nill

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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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