Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative analysis of Proprioceptive Exercises with and without Topical Glucosamine Sulfate on Pain and Functional Disability in Knee Osteoarthritis

Protocol summary

Study aim
The basic purpose of this research is to compare the effects of Proprioceptive exercises with and without topical glucosamine sulfate on knee osteoarthritis in reducing pain and functional disability.

Design
The randomized controlled trial, single-blinded study.

Settings and conduct
conducted at Muhammad physical therapy clinic and rehabilitation centre, Multan and Faiz Hospital, Multan, Pakistan,

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 45-70 years, bilateral knee OA (grade 1,2 and 3), both genders (male and female), cartilage degeneration, local biomechanical factors (e.g., joint deformity, muscle weakness), nutritional factors, postmenopausal women, and Exclusion criteria: grade 4, neurological disorders (e.g. Alzheimer's disease, Parkinson's disease), knee replacement, rheumatoid arthritis, steroidal injection in the past 2 months, neuropathy, tumor, knee fractures, knee ligament or meniscus injury, a congenital disorder of knee, diabetes mellitus > 10 years, metal implants in the knee.
Intervention groups

Intervention groups
control group-A and treatment group-B. Group-A was treated with proprioceptive exercises while group-B was treated with proprioceptive exercises with glucosamine sulfate gel

Main outcome variables
Pain functional activity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220115053712N2**
Registration date: **2022-02-28, 1400/12/09**
Registration timing: **retrospective**

Last update: **2022-02-28, 1400/12/09**
Update count: **0**

Registration date
2022-02-28, 1400/12/09

Registrant information

Name
Hifza Arif

Name of organization / entity
Muhammad Institute of Medical and Allied Sciences Multan Pakistan

Country
Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-15, 1400/09/24

Expected recruitment end date
2022-01-15, 1400/10/25

Actual recruitment start date
2021-12-15, 1400/09/24

Actual recruitment end date
2022-01-20, 1400/10/30

Trial completion date
2022-03-02, 1400/12/11

Scientific title
Comparative analysis of Proprioceptive Exercises with

and without Topical Glucosamine Sulfate on Pain and Functional Disability in Knee Osteoarthritis

Public title
Proprioceptive Exercises with and without Topical Glucosamine Sulfate in Knee Osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 4-70 years Cartilage degeneration Local biomechanical factors (e.g., obesity, joint deformity, muscle weakness) Nutritional factors Postmenopausal women Bilateral knee O.A with grade 1, 2 and 3 Both genders

Exclusion criteria:
Knee replacement Rheumatoid arthritis Steroidal injection in the past 2 months Neuropathy Tumor Knee fractures Neurological disorders (e.g., Alzheimer's disease, Parkinson's disease) OA grade 4

Age
From **45 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **39**
More than 1 sample in each individual
Number of samples in each individual: **19**
19 individuals in each group
Actual sample size reached: **30**
More than 1 sample in each individual
Actual sample size in each individual: **15**
15 individuals in each group

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation concealment occurs and patients will be recruited by using simple randomization through the Lottery method. lottery method carried out through sealed envelopes. Each participant will randomly choose the sealed envelope and open this sealed envelope.

Blinding (investigator's opinion)
Double blinded

Blinding description
In a double-blinded study, participants and investigators will be blinded. Participants will be unaware of the type of treatments that will receive and the investigator will be unaware of the type of treatment on which group which intervention will be given and for what purpose that be evaluated after the completion of the intervention trial. subjects will choose between two samples. both the samples are in the same packing. In one sample, glucosamine sulfate gel with proprioceptive exercises i.e., standing on 1 leg [eyes open and closed], knee flexion and extension exercises [sitting position with a chair and TheraBand], Walking on heel and toes [forward, backward, left, right, carioca crossover with eyes open and closed], Half squat on soft ground, Side lunge, One-legged balance exercise. In another sample, an aqueous gel with no effects for the satisfaction of subjects and proprioceptive exercises i.e., Standing on 1 leg [eyes open and closed], Knee flexion and extension exercises [sitting position with a chair and TheraBand], Walking on heel and toes [forward, backward, left, right, carioca crossover with eyes open and closed], Half squat on soft ground, Side lunge, One-legged balance exercise will be given. Subjects and investigators will be completely unaware of the type and effects of both interventions.

Placebo
Not used

Assignment
Parallel

Other design features
participants will be assessed by physical assessment and by radiological findings (x-ray)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Institutional Ethical Committee of Muhammad Institute of Medical and Allied Sciences, Multan

Street address
HBL street, near Sabzazar metro station, Bosan road, Multan, Pakistan

City
Multan

Postal code
60700

Approval date
2021-09-18, 1400/06/27

Ethics committee reference number
2021/IRB/3/physio/03

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis with grades 1, 2 and 3

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Pain

Timepoint
before and after treatment (6 weeks)
Method of measurement
Numerical Pain Rating Scale (NPRS) and Western Ontario and McMaster Universities Arthritis Index (WOMAC)

2

Description
Functional activities
Timepoint
before and after treatment (6 weeks)
Method of measurement
Numerical Pain Rating Scale (NPRS) and Western Ontario and McMaster Universities Arthritis Index (WOMAC)

Secondary outcomes

1

Description
stiffness
Timepoint
before and after treatment(6 weeks)
Method of measurement
Numerical Pain Rating Scale (NPRS) and Western Ontario and McMaster Universities Arthritis Index (WOMAC)

2

Description
muscle tone strength
Timepoint
before and after treatment(6 weeks)
Method of measurement
Numerical Pain Rating Scale (NPRS) and Western Ontario and McMaster Universities Arthritis Index (WOMAC)

3

Description
joint receptor function
Timepoint
before and after treatment(6 weeks)
Method of measurement
Numerical Pain Rating Scale (NPRS) and Western Ontario and McMaster Universities Arthritis Index (WOMAC)

Intervention groups

1

Description
Control group: Group A will be treated with only proprioceptive exercises. The proprioceptive exercises are Standing on 1 leg [eyes open and closed], Knee flexion and extension exercises (sitting position with a chair and TheraBand), Walking on heel and toes (forward, backward, left, right, carioca crossover with eyes open and closed). Half squat on soft ground, Side lunge, One-legged balance exercise. The duration of treatment is 6 weeks. The frequency of treatment is 3 times per week exercise sessions lasted 30 minutes.
Category
Other

2

Description
treatment group: Group-B will be treated with proprioceptive exercises and glucosamine sulfate. The proprioceptive exercises are Standing on 1 leg [eyes open and closed], Knee flexion and extension exercises (sitting position with a chair and TheraBand), Walking on heel and toes (forward, backward, left, right, carioca crossover with eyes open and closed). Half squat on soft ground, Side lunge, One-legged balance exercise. The duration of exercise is 6 weeks. The frequency of exercise is 3 times per week exercise sessions lasted 30 minutes. The glucosamine sulfate will apply topically twice daily, 3 times per week. the dosage of glucosamine sulfate gel will be 250mg two times a day. subjects will be instructed to clean the skin adjacent to their throbbing knee and apply the cream.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Muhammad physical therapy clinic and rehabilitation center, Multan
Full name of responsible person
Noshaba Kanwal
Street address
HBL street, near Sbzazar metro station, Bosan road, Multan, Pakistan
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2

Recruitment center
Name of recruitment center
Faiz Hospital, Multan.
Full name of responsible person
Nimra Arif
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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?
Yes

Title of funding source
Muhammad Institute of Medical and Allied Sciences, Multan

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Muhammad Institute of Medical and Allied Sciences, Multan

Full name of responsible person
Dr.Zahid Manzoor

Position
Zahid Manzoor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Demographic data and data related to final outcome will be shared by maintaining the confidentiality
When the data will become available and for how long
data will be available from Feb 2023 to March 2023 after the 6 months of publication. The data sharing plan for a clinical trial (i.e., what data will be shared when and under what conditions) will be publicly available at a third-party site that shares data with and meets the data requirements of WHO's International Clinical Trials Registry Platform; this occur before the first participant is enrolled.
To whom data/document is available
Hifza Arif(corresponding author) Senior lecturer at Ali-Ul-Murtaza Department of Rehabilitation Sciences and Muhammad Institute of Medical and Allied Sciences Multan, Pakistan
Under which criteria data/document could be used
For research purposes
From where data/document is obtainable
To the corresponding author of the study; Dr. Hifza Arif and can contact on +923097697428 hifzaa630@gmail.com can visit these search engines, you can find my study easily here https://www.researchgate.net/ https://scholar.google.com/
What processes are involved for a request to access data/document
open-access and There is the traditional public data release where anyone can get access to the data with no registration or conditions. The request will be reviewed by Director in Charge and in case of eligibility, it would be shared in two weeks.
Comments
I want randomized controlled trial registration.