

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparative analysis of Topical Glucosamine Sulfate and Proprioceptive Exercises 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 and topical glucosamine sulfate on knee osteoarthritis.

Design

The randomized clinical 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

treatment group-A and treatment group-B. Group-A was treated with topical glucosamine sulfate while group-B was treated with proprioceptive exercises.

Main outcome variables

In the management of OA proprioceptive exercises and topical glucosamine sulfate are both effective but it is expected that the effects of proprioceptive exercises in reducing the pain and functional disability in knee osteoarthritis are more as compared to topical glucosamine sulfate.

General information

Reason for update

Acronym

GS,OA

IRCT registration information

IRCT registration number: **IRCT20220115053712N1**

Registration date: **2022-02-02, 1400/11/13**

Registration timing: **retrospective**

Last update: **2022-02-02, 1400/11/13**

Update count: **0**

Registration date

2022-02-02, 1400/11/13

Registrant information

Name

Hifza Arif

Name of organization / entity

Muhammad Institute of Medical and Allied Sciences
Multan Pakistan

Country

Pakistan

Phone

+92 309 7697428

Email address

drhizaarif@mimas.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-15, 1400/08/24

Expected recruitment end date

2021-12-15, 1400/09/24

Actual recruitment start date

2021-11-15, 1400/08/24

Actual recruitment end date

2021-12-20, 1400/09/29

Trial completion date

2022-02-02, 1400/11/13

Scientific title

Comparative analysis of Topical Glucosamine Sulfate and Proprioceptive Exercises on Pain and Functional

Disability in Knee Osteoarthritis

Public title

Comparative analysis of Topical Glucosamine Sulfate and Proprioceptive Exercises on Pain and Functional Disability in Knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

bilateral knee OA with grade 1,2 and 3 Age 45-70 years
Both genders (male and female) Cartilage degeneration
Local biomechanical factors (e.g., obesity, joint deformity, muscle weakness) Nutritional factors
Postmenopausal women

Exclusion criteria:

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

Age

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

Gender

Both

Phase

4

Groups that have been masked

- Participant

Sample size

Target sample size: **38**

More than 1 sample in each individual

Number of samples in each individual: **19**

19 Individuals in both groups

Actual sample size reached: **30**

More than 1 sample in each individual

Actual sample size in each individual: **15**

15 individuals in both groups

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)

Single blinded

Blinding description

In a single-blinded study, participants will be blinded. Participants will be unaware of the type of treatments that will 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 conventional exercises i.e., ankle pumps, quadriceps isometrics, and calf stretch. In another sample, an aqueous gel with no effects for the satisfaction of subjects and proprioceptive exercises will be given. Subjects will be completely unaware of the type and effects of both interventions.

Placebo

Not used

Assignment

Parallel

Other design features

Patients were assessed by radiological finding (x-ray) and by physical assessment

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 st

Street address

HBL street, Sbzazar metro station, Bosan road, Multan, Pakistan

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Multan

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60700

Approval date

2021-09-18, 1400/06/27

Ethics committee reference number

2020/IRB/2/physio/02

Health conditions studied

1

Description of health condition studied

Knee Osteoarthritis with grade 1, 2 and 3

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

pain and functional disability

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

To reduce stiffness, muscle tone strength increases and joint receptor function raised.

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

intervention group 2; group-B will be treated with 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 [Akron, OH]), 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

Treatment - Other

2

Description

Intervention group: Group-A will be treated with topical glucosamine sulfate, ankle pumps, quads strengthening, and calf stretching. The drug will purchase from stand pharmaceuticals. The duration of treatment is 6 weeks. 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 - Drugs

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

Muhammad Institute of Medical and Allied Sciences, Multan

Full name of responsible person

Zahid Manzoor

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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, Pakistan

Full name of responsible person

Dr.Zahid Manzoor

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Name of organization / entity

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Nimra Arif

Position

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Latest degree

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Person responsible for updating data

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Noshaba Kanwal

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Other areas of specialty/work

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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

Title of my study comparative analysis of Topical Glucosamine Sulfate and Proprioceptive Exercises on Pain and Functional Disability in Knee Osteoarthritis. The basic purpose of this research is to compare the effects of Proprioceptive exercises and glucosamine sulfate on knee osteoarthritis. The expected outcome of this study is proprioceptive exercises may be more effective than glucosamine sulfate. Proprioceptive exercise may improve ADLs and reduce pain. A randomized clinical trial was conducted at Muhammad physical therapy clinic and rehabilitation center, Multan and Faiz Hospital, Multan. 30 patients were selected who met the inclusion criteria will be randomized into two groups; treatment group (A) and treatment group (B). patients were recruited by using the lottery method. Group (B) will be

treated with proprioceptive exercises and group (A) will be treated with glucosamine sulfate.

When the data will become available and for how long

This is expected that this study or data will be available at the end of this year 2022. No exact date can be expected.

To whom data/document is available

Nimra Arif

Under which criteria data/document could be used

For research purposes

From where data/document is obtainable

researchgate.net <https://scholar.google.com/hifzaa630@gmail.com>

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

open access

Comments

I want randomized clinical trial registration. please provide me as soon as possible. so that I can continue my study