

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

###### Phone

+92 309 7697428

###### Email address

drhizaarif@mimas.edu.pk

##### 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

#### **City**

Multan

#### **Postal code**

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#### **Phone**

+92 309 7697428

#### **Email**

hifzaa630@gmail.com

#### **Web page address**

<http://www.mimas.edu.pk/>

## **2**

### **Recruitment center**

#### **Name of recruitment center**

Faiz Hospital, Multan.

#### **Full name of responsible person**

Nimra Arif

#### **Street address**

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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

**Street address**

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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

**Street address**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Muhammad Institute of Medical and Allied Sciences,  
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**Full name of responsible person**

Nimra Arif

**Position**

Professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Muhammad Institute of Medical and Allied Sciences,  
Multan

**Full name of responsible person**

Noshaba Kanwal

**Position**

professor, Consultant

**Latest degree**

Medical doctor

**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**

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-UI-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.