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Mulligan’s mobilisation with movement and topical diclofenac, alone or in combination, for the management of knee osteoarthritis: a randomised controlled clinical trial

Submission date
27/10/2025

Recruitment status
No longer recruiting

Registration date
17/11/2025

Overall study status
Completed

Last Edited
17/11/2025

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Knee osteoarthritis is a common condition that causes pain, stiffness, and difficulty moving, which can make everyday activities harder and affect quality of life. Exercise is known to help and is usually the first treatment recommended. Other treatments, like a hands-on technique called the Mulligan Concept and anti-inflammatory gels such as diclofenac (Pennsaid), are also used to ease pain and improve movement.
This study looked at whether combining all three treatments—exercise, Mulligan’s technique, and diclofenac gel—would work better than using just one or two of them.

Who can participate?
Adults (45 - 75 years) diagnosed with knee osteoarthritis were invited to take part in the study.

What does the study involve?
Participants were randomly placed into one of four groups:
-One group did exercise only
-One group did exercise and received Mulligan’s technique
-One group did exercise and used diclofenac gel
-One group did all three: exercise, Mulligan’s technique, and diclofenac gel
They were assessed before treatment, two days after starting, and again at three and six months. Researchers measured pain levels, how well the knee could move, muscle strength, and overall quality of life.

What are the possible benefits and risks of participating?
Participants may experience reduced pain, better movement, and improved quality of life. Risks are expected to be low, but some people may experience mild side effects from the gel or temporary discomfort from the manual therapy.

Where is the study run from?
Democritus University of Thrace (Greece)

When is the study starting and how long is it expected to run for?
December 2020 to March 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
Protocol No. 10098/11-03-2021 (University General Hospital of Alexandroupolis Scientific Council approval)

Study information

Scientific Title
A prospective, randomized, controlled clinical study investigating the comparative and combined effects of Mulligan’s Mobilisation with Movement (MWM), topical diclofenac (Pennsaid), and their combination, alongside a standardized therapeutic exercise program, on pain, function, and quality of life in patients with knee osteoarthritis.

Acronym
KOA–MWM–NSAID

Study objectives

The combined application of Mulligan's MWM technique and topical diclofenac (Pennsaid), performed in addition to a standardized therapeutic exercise program, will produce superior improvements in pain, range of motion, muscle strength, and quality of life compared with either intervention alone or exercise only in patients with mild-to-moderate knee osteoarthritis.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/03/2021, Scientific Council of the University General Hospital of Alexandroupolis, Greece (6th km Alexandroupolis- Makris, Dragana, Alexandroupoli, 68100, Greece; +30 2551030921; secr@med.duth.gr), ref: Protocol No. 10098/11-03-2021

Primary study design
Interventional

Study design
Interventional prospective randomized controlled four-arm parallel group trial

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Osteoarthritis of the knee

Interventions
Randomisation was conducted using sealed, opaque, sequentially numbered envelopes.
The allocation sequence was generated by an independent researcher with no involvement in participant assessment or treatment. Block randomisation was applied to ensure balanced allocation across the four groups.

Group 1 (Control):
Standardised therapeutic exercise programme only (strengthening, stretching, ROM and functional activities), based on EULAR, OARSI, APTA and NICE guidelines.

Group 2 (MWM):
Mulligan's Mobilisation with Movement (pain-free tibiofemoral glides combined with active motion) + same exercise programme.
10 sessions (30 min), 3 sessions per week for 4 weeks.

Group 3 (Topical NSAID):
Topical diclofenac solution (Pennsaid) applied to the affected knee (40 drops, four times daily for 28 days) + same exercise programme.

Group 4 (Combined):
Mulligan's MWM + topical diclofenac (Pennsaid) + same exercise programme.

Intervention Type
Other

Primary outcome(s)
Pain intensity (Visual Analogue Scale, VAS) at baseline, 2 days post-intervention, 3 months, and 6 months

Key secondary outcome(s)
1. Range of motion (digital goniometer) at baseline, 2 days post-intervention, 3 months, and 6 months
2. Quadriceps and hamstring strength (hand-held dynamometer) at baseline, 2 days post-intervention, 3 months, and 6 months
3. Knee function (Knee Society Score, KSS) at baseline, 2 days post-intervention, 3 months, and 6 months
4. Health-related quality of life (EQ-5D) at baseline, 2 days post-intervention, 3 months, and 6 months

Completion date
03/09/2025

Eligibility

Key inclusion criteria
1. Diagnosed primary knee osteoarthritis (ARA/ACR criteria)
2. Kellgren–Lawrence grade ≤ 3
3. Independent ambulation (with/without aids)
4. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
45 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
250

Key exclusion criteria
1. Knee pain due to neoplasm or spine pathology
2. Psychiatric or neurological disorders
3. History of lower limb or spinal surgery

4. Intra-articular corticosteroid or hyaluronic acid injections within 6 months
5. Use of systemic corticosteroids in past 4 weeks
6. Contraindications to topical NSAIDs or manual therapy

Date of first enrolment
02/04/2021

Date of final enrolment
03/03/2025

Locations

Countries of recruitment
Greece

Study participating centre
University General Hospital of Alexandroupolis. Orthopaedic Department
6th km Alexandroupolis- Makris, Dragana
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Sponsor information

Organisation
Democritus University of Thrace

ROR
https://ror.org/03bfqnx40

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			17/11/2025	No	No
Statistical Analysis Plan			17/11/2025	No	No