ISRCTN16332782 https://doi.org/10.1186/ISRCTN16332782

The effect of sheep ghee on pain of the knee joint in older people with osteoarthritis of the knee

Submission date
03/03/2025

Recruitment status
No longer recruiting

Registration date
07/03/2025

Overall study status
Completed

Last Edited
07/03/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis, the most common joint disease, often affects the knee and causes pain, stiffness, and limited motion. This condition lowers the quality of life and increases healthcare costs, especially for the elderly. Treatments include medications, topical applications, and surgery, but painkillers can have side effects. Natural remedies like sheep ghee, used traditionally in Iran for burns and wounds, may offer a safer alternative. Sheep ghee contains components that reduce inflammation and aid in healing. This study aims to evaluate the effects of sheep ghee on knee osteoarthritis symptoms in elderly patients, given its cultural use and lower risk of complications.

Who can participate?
Adult patients with knee osteoarthritis

What does the study involve?
Participants are randomly allocated into intervention, placebo and control groups. The intervention group applied 1g of sheep ghee to the painful areas of their knees twice daily for a month. A food laboratory verified the ghee's quality. Each participant received 60g of ghee and Vaseline and was instructed to massage the painful areas for 1 minute without covering them. The placebo group used Vaseline in the same way, while the control group only performed the one-minute massage. All participants continued their usual medications, and researchers made daily phone calls to ensure the instructions were followed correctly.

What are the possible benefits and risks of participating?
Possible Benefits:
1. Pain Relief: Participants may experience a reduced knee pain associated with osteoarthritis.
2. Improved Physical Function: The study may enhance daily activities and overall physical functioning of the knee joint.
3. Increased Range of Motion: Participants might notice an improvement in their knee’s range of motion, facilitating better movement and flexibility.
4. Natural Treatment: Since the study focuses on sheep ghee, participants might benefit from a natural approach that could complement their existing treatment plans.

5. Contributing to Research: Participants will contribute to valuable research that may help others suffering from knee osteoarthritis in the future.

Possible Risks:
1. Limited Follow-Up Duration: While this study is the first to evaluate this topical formulation for knee osteoarthritis, a longer follow-up could have provided insights into symptom recurrence and possible adverse events from ghee
2. Disruption of Current Treatment: Participants may find that introducing sheep ghee affects their existing treatment plans, leading to complications if not monitored adequately.
3. Individual Differences: The effectiveness of the intervention can vary based on individual health conditions, making results unpredictable.

Where is the study run from?
School of Nursing and Midwifery, Rafsanjan University of Medical Sciences, Iran

When is the study starting and how long is it expected to run for?
February 2020 to October 2022

Who is funding the study?
Rafsanjan University of Medical Sciences, Iran

Who is the main contact?
Dr Hadi Khoshab, hadikhoshab@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Hadi Khoshab

ORCID ID
https://orcid.org/0000-0001-5336-4973

Contact details
School of Nursing and Midwifery, Bam University of Medical Sciences
Bam
Iran
7616767687
+989132425700
hadikhoshab@gmail.com

Additional identifiers

Study information

Scientific Title
The effect of sheep ghee on pain, stiffness, physical function, and range of motion of the knee joint in older people with osteoarthritis of the knee

Study objectives
Topical application of sheep ghee reduces knee joint pain.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/02/2020, Rafsanjan University of Medical Sciences (Central Organization of Rafsanjan University of Medical Sciences, Rafsanjan, 7717933777, Iran; +98 03434280038; edu@rums.ac.ir), ref: IR.RUMS.REC.1398.202

Study design
Non-randomized quasi-experimental design

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Assessing changes in knee joint stiffness, pain, range of motion, and physical function after the use of ghee in elderly people affected by osteoarthritis.

Interventions
The intervention group applied 1g (equivalent to a small ice cream spoon) of sheep ghee on painful areas (front, side, and back) of the knee twice daily in the morning and at night for a month. A food laboratory confirmed the quality of ghee. For one month, patients received 60g of ghee and Vaseline. They were instructed to massage painful areas for one minute without covering them. The placebo group used Vaseline the same way as the intervention group in equal doses. The control group received only one-minute massage, and all three groups continued to take their previous medications. Daily phone calls were made to the participants to ensure that the intervention was being carried out correctly.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sheep ghee, vaseline

Primary outcome(s)
Pain is measured using the Visual Analogue Scale (VAS) before and immediately after the intervention

Key secondary outcome(s))
1. The range of motion for the knee joint is measured using the distance from the heel to the thigh with a ruler before and immediately after the intervention

2. The condition of patients with knee osteoarthritis, including pain, stiffness, and physical functioning of the joints, is measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) before and immediately after the intervention. This questionnaire evaluates three subscales on a Likert scale (None, Mild, Moderate, Severe, Extreme): 1) assessment of knee pain over the past 48 hours, 2) joint stiffness, and 3) physical function in the last 48 hours.

Completion date
01/10/2022

Eligibility

Key inclusion criteria
1. No injury, open wound or skin disease in the knee
2. No recent injury to the affected knee
3. No alcohol or drug addiction
4. No use of other complementary methods such as physiotherapy, acupuncture or percutaneous electrical nerve stimulation
5. No history of knee surgery
6. Insensitivity to Vaseline and sheep ghee
7. No mental illness and cognitive disorder
8. Ability to see and walk
9. Ability to communicate
10. Mild to moderate pain score in VAS (Visual Analogue Scale)
11. No history of intra-articular corticosteroid or hyaluronic acid injection for the past three months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Upper age limit
85 years

Sex
All

Total final enrolment
85

Key exclusion criteria
Not meeting the participant inclusion criteria

Date of first enrolment
01/09/2021

Date of final enrolment
01/09/2022

Locations

Countries of recruitment
Iran

Study participating centre
Rafsanjan University of Medical Sciences
Central Organization of Rafsanjan University of Medical Sciences
Rafsanjan
Iran
7717933777

Sponsor information

Organisation
Rafsanjan University of Medical Sciences

ROR
https://ror.org/01v8x0f60

Funder(s)

Funder type
University/education

Funder Name
Rafsanjan University of Medical Sciences

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype

Universities (academic only)

Location
Iran

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Hadi Khoshab, hadikhoshab@gmail.com. Except for the demographic characteristics of the participants and their identity, all required information will be available upon request from the corresponding author.

IPD sharing plan summary
Available on request