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A study on pain relieving property of a herbal lotion for joint pains

Submission date
13/11/2025

Recruitment status
Recruiting

Registration date
06/01/2026

Overall study status
Ongoing

Last Edited
06/01/2026

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Joint and muscle pain are very common problems that can affect people of all ages, especially older adults. These pains can result from arthritis, injuries, or daily wear and tear of joints. Many pain relief medicines can cause unwanted side effects when taken orally. Therefore, topical herbal products that are applied directly to the skin are becoming popular because they can relieve pain locally with fewer side effects.
Ortho Shield Herbal Lotion, developed by Fadna Life Science (Pvt) Ltd., is a natural herbal lotion made from coconut oil, aloe vera, peppermint, gaultheria oil, black pepper, chili pepper, and lemongrass, all known for their pain-relieving and anti-inflammatory properties.
The aim of this study is to find out whether applying Ortho Shield Herbal Lotion can effectively reduce joint pain, improve mobility, and enhance quality of life, while ensuring it is safe and well-tolerated.

Who can participate?
Adults between 20 and 70 years of age who have mild to moderate arthritis or muscle and joint pain lasting for more than two weeks can take part.
People will not be able to take part if they have serious illnesses (such as lupus, rheumatoid arthritis, or HIV), are pregnant or breastfeeding, are already using other pain-relieving creams or drugs, or have known allergies to any of the lotion’s ingredients.

What does the study involve?
This is an open-label clinical trial, meaning both participants and researchers will know what treatment is being used.
Each participant will apply Ortho Shield Herbal Lotion twice a day (morning and evening) for two weeks, using 1 g for small joints and 2 g for large joints each time. Before application, the area will be warmed with hot water.
Participants will be monitored closely for any skin reactions, and their pain levels will be measured using questionnaires before, during, and after the treatment. The total study period for each person, including follow-up, will be six weeks.

What are the possible benefits and risks of participating?
Possible benefits:

• Relief from joint and muscle pain.
• Improved movement and quality of life.
• Access to a natural herbal product at no cost.
• Regular health monitoring during the study.
Possible risks:
• Mild skin irritation, redness, or itching.
• These effects are expected to be rare and temporary. If they occur, treatment will be stopped immediately, and medical care will be provided.

Where is the study run from?
The trial will be conducted at:
• National Ayurveda Hospital, Colombo 08 and
• Unit of Research and Development of Natural Products, Faculty of Indigenous Medicine, University of Colombo, Sri Lanka.

When is the study starting and how long is it expected to run for?
December 2025 to June 2026.

Who is funding the study?
The study is funded and supported by Fadna Life Science (Pvt) Ltd., Sri Lanka, in collaboration with the Faculty of Indigenous Medicine, University of Colombo, Sri Lanka.

Who is the main contact?
Dr Jeevani Dahanayake (jeevanimd@iim.cmb.ac.lk).

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Principal investigator

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Additional identifiers

Study information

Scientific Title
Evaluation of the efficacy of Orthosheild lotion for joint pains: An open-label clinical trial

Acronym
OSJpains

Study objectives
To evaluate the efficacy, safety, and tolerability of Ortho Shield Herbal Lotion in patients with mild to moderate joint pain. The study aims to determine whether the topical herbal preparation can effectively reduce pain and improve quality of life, while remaining safe and well-tolerated.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/06/2025, Ethics Reveiw Committee- Faculty of Indigenous Medicine (ERCFIM) (Faculty of Indigenous Medicine, University of colombo, Timbirigasyaya, 10100, Sri Lanka; +94112692395; ethicsreview@fim.cmb.ac.lk), ref: ERC 25/268

Study design
Open-label single arm clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Joint pain and musculoskeletal discomfort

Interventions
This is a single-arm open-label clinical trial conducted among patients diagnosed with mild to moderate joint pain. Eligible participants will apply Ortho Shield Herbal Lotion twice daily (morning and evening) for two weeks. The dosage will be 1 g for small joints and 2 g for large joints per application, applied after warming the affected area with hot water.
Participants will be assessed for pain reduction and improvement in quality of life using validated questionnaires (e.g., the McGill Pain Questionnaire) at baseline and after completion of the two-week intervention. Vital signs (blood pressure and heart rate) will be measured at baseline and on day 15. Any skin sensitivity reactions will be monitored through a pre-study skin

prick test and continuous observation during the trial.
Follow-up assessments will be conducted four weeks after the completion of treatment to evaluate sustained effects and monitor any delayed adverse events.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Ortho Shield Herbal Lotion

Primary outcome(s)
1. Reduction in joint pain intensity measured using the McGill Pain Questionnaire at baseline and after two weeks of intervention.
2. Improvement in overall quality of life scores (QOL) assessed before and after treatment.

Key secondary outcome(s))
1. Assessment of skin sensitivity and local adverse reactions (e.g., redness, itching, swelling).
2. Change in blood pressure and heart rate before and after the intervention.
3. Participant-reported satisfaction and functional improvement scores.

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Adults aged 20–70 years, of either sex.
2. Diagnosed with mild to moderate arthritis or musculoskeletal pain for more than two weeks.
3. Willing to provide written informed consent.
4. Able to comply with the study protocol and follow-up schedule.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
20 years

Upper age limit
70 years

Sex

All

Total final enrolment
0

Key exclusion criteria
1. Patients with serious systemic illnesses (e.g., rheumatoid arthritis, lupus, HIV).
2. Pregnant or breastfeeding women.
3. Patients currently using other pain-relieving topical or systemic medications.
4. Known hypersensitivity or allergy to any component of the lotion.
5. Presence of open wounds or infections at the application site.

Date of first enrolment
15/12/2025

Date of final enrolment
01/04/2026

Locations

Countries of recruitment
Sri Lanka

Study participating centre
National Ayurveda Teaching Hospital
No 325,Dr. N.M.Perera Mawatha
Colombo
Sri Lanka
10100

Study participating centre
Traditional Medicine Treatment Unit
Faculty of Indigenous medicine, University of Colombo
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Sponsor information

Organisation
Fadna Life Sciences

Funder(s)

Funder type
Not defined

Funder Name
Fadna Life Sciences

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be available upon reasonable request from Dr Jeevani Dahanayake (jeevanimd@iim.cmb.ac.lk). Participant data sheets will not contain any personal identifiers or contact information.
All data entry and study management systems used at the clinical sites will remain secured and password protected. At the end of the study, all datasets will be de-identified and archived in compliance with institutional data protection policies. Access to raw data will be granted under the above conditions, following review and approval by the principal investigator.
Study Outputs
The expected study outputs include:
1. Evidence-based evaluation of the efficacy and safety of Ortho Shield Herbal Lotion in the management of joint pain.
2. Publication of findings in a peer-reviewed journal.
3. Dissemination of results at academic and clinical research conferences.
4. Contribution to the development and standardization of herbal topical analgesics in Sri Lanka.

IPD sharing plan summary
Available on request