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Clinical study to evaluate the effect of Beam Fiel ointment on fungal skin conditions

Submission date
13/11/2025

Recruitment status
Recruiting

Registration date
17/11/2025

Overall study status
Ongoing

Last Edited
04/12/2025

Condition category
Infections and Infestations

[X] 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
Fungal skin infections are common worldwide and often cause itching, redness, and discomfort. Many chemical antifungal medicines may lead to side effects or resistance, so herbal remedies are becoming more popular as safer alternatives. Beam Fiel ointment, marketed by Beam Hela Osu (Pvt) Ltd, is an Ayurvedic herbal formulation used for over 30 years in Sri Lanka to treat various fungal skin conditions such as ringworm, tinea, and white patches. It is made from Senna alata leaves, Curcuma longa rhizomes, and coconut oil, which are known for their antifungal, anti-inflammatory, and healing properties. The purpose of this study is to evaluate whether Beam Fiel ointment can safely and effectively reduce fungal infections, relieve symptoms like itching and scaling, promote skin healing, and prevent recurrence, providing scientific evidence to support its traditional use in Ayurveda practice.

Who can participate?
Patients between 18 and 80 years of age with fungal infection

What does the study involve?
Each participant will apply Beamfiel ointment twice a day (morning and evening) for 3 months as a thin layer of at least 2 FTU (Fingertip Units) directly to the lesions and 2 cm beyond the lesions. Before application, the area will be warmed with hot water. Participants will be monitored closely for any skin reactions. Clinical parameters such as lesion size (BSA), erythema, scaling, and pruritis will be measured before and after treatment using a 0–3 grading scale. The total score will be calculated by adding these grades. Fungal infection will be confirmed and photographs will be taken without revealing patient identity. The total study period for each person, including follow-up, will be 4 months.

What were the possible benefits and risks of participating?
Possible benefits:
1. Decrease in the size of the skin lesions, itching and redness
2. Improved movement and quality of life
3. Access to a natural herbal product at no cost
4. Regular health monitoring during the study
Possible risks:

1. Mild discomfort, burning sensation and irritation
2. 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:
1. National Ayurveda Hospital, Borella
2. 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?
The total study duration is four months per participant, three months of treatment followed by a one month follow-up period. Recruitment and study activities will begin after receiving ethical approval from the Ethics Review Committee, Faculty of Indigenous Medicine, University of Colombo.

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

Who is the main contact?
Prof. Swarna Hapuarachchi, dr.sdhapuarachchi@fim.cmb.ac.lk

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Study information

Scientific Title
Single-arm, open-label intervention study to investigate the efficacy of herbal fungicidal Beam Fiel ointment on fungal infections and skin conditions

Study objectives
To evaluate the efficacy, safety, and tolerability of Beamfiel Ointment in patients with fungal skin infections.
The study aims to determine whether the topical herbal preparation can effectively reduce fungal skin infections and improve quality of life, while remaining safe and well-tolerated.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 26/08/2025, Ethics Review Committee, Faculty of Indigenous Medicine, University of Colombo (Faculty of Indigenous Medicine, University of Colombo, Rajagiriya, Colombo, 10100, Sri Lanka; +94 (0)112692395; ethicsreview@fim.cmb.ac.lk), ref: ERC 25/274

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Diagnostic, Screening, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Fungal skin infections

Interventions
This is a single-arm open-label clinical trial conducted among patients diagnosed with mild to moderate fungal skin infections. Eligible participants will apply Beamfiel ointment twice a day (morning and evening) for 3 months. The medications will be applied as a thin layer of at least 2 FTU (Fingertip Unit) directly to the lesions and 2 cm beyond the lesions. Before application, the area will be warmed with hot water. Participants will be assessed for reduction of the skin lesion and improvement in quality of life. KOH Mount test will be done at baseline and after completion of the three months intervention. Any skin sensitivity reactions will be monitored and continuous observation during the trial. Follow-up assessments will be conducted 3 months after the completion of treatment to evaluate sustained effects and monitor any delayed adverse events.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Beamfiel Ointment (containing Senna alata leaves, Curcuma longa rhizomes, and coconut oil)

Primary outcome(s)
1. Fungal skin infections intensity measured using KOH Mount test at baseline and after 3 months

2. Lesion size (BSA), erythema, scaling, and pruritis measured using 0–3 grading scale at before and after treatment

Key secondary outcome(s))
1. Skin sensitivity and local adverse reactions (e.g., redness, itching, swelling) measured using skin sensitivity test at before the treatment

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Male and female participants between the ages of 18–80 years
2. Participants with positive Potassium Hydroxide (KOH) mount test
3. Participants confirmed by KOH mount test with the fungal skin lesion of ≤3% of their Body Surface Area (BSA), except face and neck

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Individuals with hypersensitivity (type I, II, III and IV) to topical application
2. Individuals who are receiving any other local application for skin diseases
3. Immunocompromised individuals
4. Individuals with hypertension, diabetes mellitus and dyslipidemia
5. Individuals with chronic skin conditions like eczema, psoriasis, or dermatitis in the affected area
6. Individuals with secondary bacterial infections
7. Individuals in another clinical trial
8. Pregnant mothers, lactating mothers and children

Date of first enrolment
15/12/2025

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
Sri Lanka

Sponsor information

Organisation
Beam Hela Osu (Pvt) Ltd

Funder(s)

Funder type

Funder Name
Beam Hela Osu (Pvt) Ltd

Funder Name
University of Colombo

Alternative Name(s)
University of Colombo, Sri Lanka, UoC

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sri Lanka

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available