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The use of moist exposed burn ointment in the treatment of ringworm among Filipinos

Submission date
09/10/2025

Recruitment status
No longer recruiting

Registration date
09/10/2025

Overall study status
Completed

Last Edited
09/10/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Tinea corporis is a fungal skin infection that typically appears as a circular, scaly rash with a red border, often clearing in the center. Topical antifungals are the primary treatment for localized infections. On the other hand, moist exposed burn ointment (MEBO) is a herbal-based oil product developed in China, used as an alternative treatment for various conditions like burns, diabetic wounds, ulcers, and more. Research suggests it provides pain relief, fights infections, and promotes healing by stimulating new blood vessel formation and supporting tissue repair. Due to limited topical antifungals available in the Philippines, alternative treatment for this condition is warranted. Hence, this study was proposed.

Who can participate?
Filipino patients of either sex, aged 12 to 75 years old, with tinea corporis

What does the study involve?
Participation in this research is entirely voluntary. The participants have the right to withdraw at any point in the study.
After providing informed consent to participate, the primary investigator will interview the participant, conduct a physical examination, and gather medical details. There will be three check-ups: at the start, and then after 4 and 8 weeks of treatment. During each visit, the following will occur: First, answer questions about the severity of itchiness. Second, the primary investigator will take pictures of the affected skin. Third, a certified dermatologist will assess the skin issues. Additionally, skin samples will be taken by scraping to check for the presence of the fungal elements causing the problem.
The participant will then be randomly assigned to either Group A or B. The medication will be provided at no cost and will be replenished if needed at every follow-up. Before applying the medication, clean the affected areas with the provided mild soap for 30 seconds. Then, apply the designated topical medication to the affected areas twice daily for 4 to 8 weeks. Any adverse events, such as increased redness or worsening itchiness or burning sensation, should be reported at each follow-up.
Throughout the study, the participant is not allowed to use home remedies or any commercially available oral or topical medications, specifically antihistamines, corticosteroids, and antifungals which will be provided on a separate sheet.

At the end of the treatment, the participant will complete a questionnaire about their overall satisfaction with the treatment.

What are the possible benefits and risk of participating?
The skin condition may improve significantly with less or minimal risk. The participation will likewise indirectly help dermatologists in search for better and effective alternative treatment for tinea corporis.
The results may be temporary or permanent and there is no way to predict how long the results will last. Although these treatments may be effective in most cases, no guarantee can be made. During treatment, the participants may experience the following adverse effects: redness, itchiness, burning sensation, swelling, and vesicles.

Where is the study run from?
The study is being run from the Department of Dermatology, Jose R. Reyes Memorial Medical Center (JRRMMC) in Manila, Philippines.
All consultations, treatment applications, and follow-up assessments will take place at the Dermatology Outpatient Department of JRRMMC.

When is the study starting and how long is it expected to run for?
October 2023 to June 2025

Who is funding the study?
This study is financed by the primary investigator's personal funds. Neither the primary investigator nor the co-investigators will receive any form of sponsorship from the distributor or manufacturer of MEBO or ketoconazole 2% cream.

Who is the main contact?
Dr Angeli Carina Lahoz, lahozac@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Angeli Carina Lahoz

ORCID ID
https://orcid.org/0009-0009-8005-0991

Contact details
Jose R. Reyes Memorial Medical Center
Department of Dermatology
Rizal Avenue
Sta. Cruz
Manila
Philippines
1003
+63 (0)9088756183
lahozac@gmail.com

Additional identifiers

Protocol serial number
2023-168

Study information

Scientific Title
An assessor-blinded, randomized controlled trial on the efficacy and safety of moist exposed burn ointment versus ketoconazole 2% cream in the treatment of tinea corporis among Filipinos

Study objectives
There is no significant difference in the efficacy and safety between moist exposed burn ointment (MEBO) and ketoconazole 2% cream in the treatment of tinea corporis among Filipinos.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/01/2024, Jose R. Reyes Memorial Medical Center - Institutional Review Board (Rizal Avenue, Sta. Cruz, Manila, 1003, Philippines; +63 (0)287321071; jrrmmc.irb@gmail.com), ref: 2023-168

Primary study design
Interventional

Study design
Assessor-blinded randomized controlled trial

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Tinea corporis

Interventions
The statistician employs a computer-generated randomization technique to allocate the participants randomly into two groups: Group A and Group B. Group A receive MEBO treatment, while Group B receive ketoconazole 2% as control.

Two board-certified dermatologists who are not associated with the study are blinded and responsible for assessing the clinical severity of the subjects using the physician global assessment.

Participants in both groups receive specific instructions for their treatment regimen. They are directed to cleanse the affected areas with the provided mild soap for 30 seconds. Following this, they apply their designated topical treatments to the affected areas twice daily for a period of 4 to 8 weeks.

Statistical analysis plan:
Categorical data will be presented as frequencies and percentages, while continuous data will be summarized as means and standard deviations.

The Student's t-test will be used to compare means of continuous variables between groups, and the paired t-test to compare means within groups. The Pearson's chi-squared test of independence will assess associations between categorical variables and treatment groups.

A 5% significance level ($p < 0.05$) will be used for all analyses. Statistical analyses will be performed using STATA version 16.1 and Microsoft Excel.

Intervention Type
Other

Primary outcome(s)
1. Clinical response assessed using the Physician's Global Assessment (PGA) based on induration, erythema, and scaling
2. Mycological cure determined by potassium hydroxide (KOH) examination under direct microscopy, evaluating the presence and quantity of hyphae
Measurements will be conducted at baseline, week 4, and week 8.

Key secondary outcome(s)
1. •Patient-reported pruritus evaluated using the 5-D Pruritus Scale at baseline, week 4, and week 8
2. Treatment satisfaction score measured by the treatment satisfaction questionnaire for medication (TSQM-9) at the end of the study

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Filipino
2. Either sex
3. Aged 12 to 75 years old
4. Clinically diagnosed tinea corporis and confirmed by by the presence of long, narrow, septated and branching hyphae on microscopic examination of skin scrapings in 10% KOH preparation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Lower age limit
12 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
35

Key exclusion criteria
1. Patients with lesions involving more than 20% of total body surface area
2. Those with concomitant active, localized, or systemic infection
3. Those with concurrent dermatoses
4. Individuals in an immunocompromised state
5. Patients who had used topical and systemic steroids, immunomodulating drugs, keratolytic agents, or topical and systemic antifungals within the last 30 days
6. Individuals with known or suspected hypersensitivity to azoles, Coptidis rhizome, Phellodendri chinensis cortex, Scutellariae radix, sesame oil and beeswax

Date of first enrolment
23/05/2024

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
Philippines

Study participating centre
Jose R. Reyes Memorial Medical Center
Department of Dermatology
Rizal Avenue
Sta. Cruz
Manila
Philippines
1003

Sponsor information

Organisation
José R. Reyes Memorial Medical Center

ROR

https://ror.org/023gzq092

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The information collected from participants will be stored securely by the study team for 10 years. Only the investigators will have access to these data, which will be used solely for this research.
Because the data contain personal health information, they will not be shared publicly. However, anonymized or summarized data may be shared with other researchers upon reasonable request and with approval from the Jose R. Reyes Memorial Medical Center Research Ethics Review Committee.
All data will be destroyed after 10 years.

IPD sharing plan summary
Available on request