STUDY PROTOCOL

Cure, sleep and treatment satisfaction with topical sulfur 7% versus permethrin 5% in scabies: a randomized open-label trial

ClinicalTrials.gov Identifier: NCT_____ (to be assigned upon registration)

Document Date: 07 September 2026

Version: 1.0

Sponsor-Investigator: Can Tho University of Medicine and Pharmacy / Can Tho Dermatology Hospital, Can Tho City, Viet Nam

1. Background and Rationale

Scabies is a highly pruritic skin infestation caused by Sarcoptes scabiei var. hominis that remains endemic in many resource-limited settings, including southern Viet Nam. Topical permethrin 5% cream is recommended as first-line therapy in most international guidelines, but reports of reduced efficacy have accumulated in some regions. Sulfur-based preparations are inexpensive and widely used, particularly where permethrin is costly or unavailable, but head-to-head comparative data are limited and patient-centred outcomes such as sleep and treatment satisfaction are rarely assessed alongside parasitological cure.

This protocol describes a randomized, open-label, comparative trial designed to evaluate the efficacy, tolerability, patient-reported outcomes and cost of topical sulfur 7% cream versus permethrin 5% cream in adults with ordinary scabies.

2. Objectives

To compare topical sulfur 7% cream and permethrin 5% cream in adults with scabies with respect to: (i) complete cure at weeks 2 and 4; (ii) change in pruritus severity; (iii) change in sleep quality and insomnia symptoms; (iv) treatment satisfaction; (v) incidence of treatment-related adverse events; and (vi) direct treatment cost.

3. Study Design

Randomized, open-label, two-arm, parallel-group, active-comparator trial conducted at Can Tho Dermatology Hospital, Can Tho City, Viet Nam. Enrolment and follow-up were conducted between June 2024 and June 2026. Participants were allocated 1:1 by sealed lots drawn at enrolment. Because the two study creams differ in appearance, packaging and application schedule, masking of participants and treating clinicians was not feasible; outcome assessment relied on standardized clinical criteria and validated patient-reported instruments to limit assessment bias.

4. Study Population

4.1 Inclusion Criteria

- Adults aged 18 years or older.

- Clinical diagnosis of ordinary (non-crusted) scabies, established using the 2020 International Alliance for the Control of Scabies (IACS) consensus criteria, category B: (B1) burrow identified; or (B2) typical lesions at male genitalia; or (B3) typical lesions at typical sites plus pruritus and a history of close contact with a person with scabies or itch.

4.2 Exclusion Criteria

- Known allergy or intolerance to sulfur or permethrin.
- Breastfeeding.
- Hearing, visual, or cognitive impairment preventing reliable self-reporting of symptoms.
- Self-discontinuation of study treatment before completion of follow-up.

5. Sample Size

Sample size was calculated using the two-proportion formula with a two-sided significance level (alpha) of 0.05 and 80% power, yielding a target of 45 participants per arm (total N = 90).

6. Randomization

Ninety eligible participants were allocated 1:1 to the two treatment arms by sealed lots drawn at the time of enrolment. Allocation concealment was maintained until the point of assignment; the trial was open-label thereafter.

7. Interventions

7.1 Arm A: Sulfur 7% cream (n = 45)

Applied from the neck to the soles once each evening, left on the skin for 8-14 hours, then washed off, on three consecutive days.

7.2 Arm B: Permethrin 5% cream (n = 45)

Applied from the neck to the soles as a single overnight application, left on the skin for 8-14 hours, then washed off, and repeated once after 7 days.

In both arms, participants received standardized written and verbal instructions on application technique and on decontamination of clothing, bedding and towels (hot-water laundering or sealing for 7 days); the same treatment regimen was offered to household contacts.

8. Outcome Measures and Assessment Schedule

Participants were assessed at baseline (week 0), week 2 and week 4.

8.1 Primary Outcomes

- Complete cure at week 4, defined per the 2017 European guideline as resolution of pruritus with no active lesions and no new lesions on clinical examination.
- Complete cure at week 2, using the same definition.

8.2 Secondary Outcomes

- Pruritus severity, measured by a verbal rating scale (0-4), at baseline, week 2 and week 4.
- Sleep quality and insomnia symptoms, measured by the Athens Insomnia Scale (AIS, 8 items, range 0-24), at baseline and week 2.
- Insomnia prevalence, defined by the validated AIS cutoff, at baseline and week 2.
- Treatment satisfaction, measured by the 9-item Treatment Satisfaction Questionnaire for Medication (TSQM-9; domains: effectiveness, convenience, global satisfaction; each scored 0-100), at week 4.
- Treatment-related adverse events (e.g., skin burning, irritation, contact dermatitis), assessed at week 2 and week 4.
- Direct treatment cost per participant, converted to US dollars, assessed at week 4.

9. Statistical Analysis

A detailed, pre-specified statistical analysis plan is provided as a separate document accompanying this protocol.

10. Ethical Considerations

The study was approved by the institutional research ethics committee of Can Tho University of Medicine and Pharmacy (approval number 26.041.HV/PCT-HĐĐĐ-ĐC). Written informed consent was obtained from all participants prior to enrolment. This trial is being registered retrospectively on ClinicalTrials.gov; no changes to the originally approved protocol, eligibility criteria, interventions or outcome measures have been made as a result of this registration.

11. Investigator and Study Site

Can Tho Dermatology Hospital and Can Tho University of Medicine and Pharmacy, Can Tho City, Viet Nam.