STATISTICAL ANALYSIS PLAN

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

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

1. Purpose

This Statistical Analysis Plan (SAP) specifies, in advance of unblinded analysis, the statistical methods used to evaluate the primary and secondary outcomes of the trial comparing topical sulfur 7% cream and permethrin 5% cream in adults with scabies, as described in the accompanying Study Protocol.

2. Study Design Summary

Randomized, open-label, two-arm, parallel-group trial; 90 participants allocated 1:1 (45 per arm); assessments at baseline, week 2 and week 4.

3. Hypotheses

The trial was designed as a comparative (superiority-exploratory) study without a pre-specified non-inferiority or equivalence margin. The null hypothesis for each outcome is that there is no difference between sulfur 7% and permethrin 5% cream; two-sided testing was used throughout.

4. Analysis Populations

- Intention-to-treat (ITT) population: all randomized participants analysed according to their assigned arm.
- All 90 randomized participants completed follow-up with no loss to follow-up; the ITT and per-protocol populations are therefore identical (45 vs. 45).

5. General Statistical Considerations

The Shapiro-Wilk test was used to assess normality of continuous variables. As outcome data were found to be non-normally distributed, non-parametric methods were used throughout. A two-sided p-value < 0.05 was considered statistically significant. All analyses were performed using SPSS version 26.0.

6. Analysis of Primary Outcomes

Complete cure rates at week 2 and week 4 were summarized as proportions with 95% confidence intervals calculated by the Wilson method, and compared between arms using the chi-square test or Fisher's exact test as appropriate for cell size.

7. Analysis of Secondary Outcomes

- Pruritus severity and Athens Insomnia Scale (AIS) scores: summarized as mean and standard deviation (or median and interquartile range where appropriate); between-arm comparisons by the Mann-Whitney U test; within-arm change over time by the Wilcoxon signed-rank test.
- Insomnia prevalence (AIS cutoff): compared between arms using the chi-square test or Fisher's exact test.
- TSQM-9 domain scores (effectiveness, convenience, global satisfaction): summarized as mean and standard deviation; compared between arms using the Mann-Whitney U test.
- Incidence of treatment-related adverse events: compared between arms using the chi-square test or Fisher's exact test.
- Direct treatment cost (US dollars): summarized as mean and standard deviation (or median and interquartile range); compared between arms using the Mann-Whitney U test.
- Association between reduction in pruritus and improvement in AIS score from baseline to week 2: assessed using Spearman's rank correlation coefficient.

8. Handling of Missing Data

All 90 randomized participants had complete data for all scheduled assessments; no imputation for missing data was required.

9. Subgroup and Sensitivity Analyses

No subgroup or sensitivity analyses were pre-specified or performed.

10. Software

All statistical analyses were performed using SPSS Statistics version 26.0 (IBM Corp.).