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Efficacy and safety of topical spironolactone for treating mild to moderate acne vulgaris: A systematic review with meta- analysis

Dereiah, S; Ghori, MU; Conway, BR.

Corresponding author:
Barbara R. Conway

b.r.conway@hud.ac.uk

Author Affiliation:
University of Huddersfield, UK.

ADMINISTRATIVE INFORMATION

Support - University of Huddersfield.

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Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 May 2025 and was last updated on 29 May 2025.

INTRODUCTION

Review question / Objective This systematic review and meta-analysis aim to evaluate the efficacy and safety of topical spironolactone in the treatment of acne vulgaris by evaluating data from published clinical studies.

Rationale Acne is a prevalent dermatological condition with significant psychosocial and medical implications, necessitating effective and well-tolerated treatment options. While systemic spironolactone has been usually used for acne management due to its anti-androgenic properties, its topical formulation offers a potentially safer alternative with fewer systemic side effects. However, its clinical effectiveness has not been fully established. This review will focus on clinical studies evaluating topical spironolactone's effectiveness. The findings will provide an evidence base for dermatologists and researchers to assess the potential of topical spironolactone as an alternative or adjunctive acne treatment.

Condition being studied To evaluate the efficacy and safety of topical SP formulations for mild to moderate acne.

METHODS

Search strategy A systematic literature search was conducted across several databases (PubMed, Scopus, the Meta-Register of Controlled Trials, the US National Institutes of Health Ongoing Trials Register, the Australian New Zealand Clinical Trials Registry, the World Health Organization International Clinical Trials Registry Platform, Google Scholar, and the EU Clinical Trials Register) using PRISMA guidelines to identify clinical studies evaluating topical SP for acne vulgaris.

Participant or population Patients with acne vulgaris affecting the face and other parts of the body.

Intervention Topical spironolactone preparations with no limitation on the applied delivery system.

Comparator Topical spironolactone gel formulations compared with controls.

Study designs to be included Clinical studies including randomised double-blind clinical trial, single arm trial, open-label clinical trial and a split-face trial.

Eligibility criteria The inclusion and exclusion criteria for this systematic review and meta-analysis were defined using the PICOS (Population, Intervention, Comparison, Outcome, and Study Design) framework. Eligible studies included patients with acne vulgaris affecting the face and/or body, while those with additional skin diseases were excluded to avoid confounding. The intervention criteria focused on topical spironolactone, excluding systemic or oral spironolactone and its use for non-acne conditions. Only studies comparing different topical spironolactone gel formulations were included, excluding those comparing placebo or vehicle-only treatments. The primary outcome measures were Total Lesion Count (TLC) and Acne Severity Index (ASI), with studies lacking these clinical outcomes were excluded.

Information sources PubMed, Scopus, the Meta-Register of Controlled Trials, the US National Institutes of Health Ongoing Trials Register, the Australian New Zealand Clinical Trials Registry, the World Health Organization International Clinical Trials Registry Platform, Google Scholar, and the EU Clinical Trials Register.

Main outcome(s) To evaluate the efficacy and safety of topical SP formulations for mild to moderate acne. The findings will provide an evidence base for dermatologists and researchers to assess the potential of topical spironolactone as an alternative or adjunctive acne treatment.

Data management The data will be organised using Microsoft Excel and stored using the One-Drive system on the University of Huddersfield's secured server.

Quality assessment / Risk of bias analysis The risk of bias assessment for the eligible studies was conducted using the revised Cochrane Risk of Bias assessment tool (RoB 2.0, version 2019). This framework evaluates bias across five key domains: D1 (randomisation process), D2 (deviations from intended interventions), D3 (missing outcome data), D4 (measurement of the outcome), and D5 (selection of reported results).

Strategy of data synthesis Studies were selected based on the PICOS criteria, and data from the identified studies were analysed using qualitative and quantitative approaches. The primary efficacy outcomes were total lesion count (TLC) and acne severity index (ASI), while safety was assessed based on the reported adverse effects.

Subgroup analysis There was heterogeneity in the clinical outcomes defined by various studies, which necessitated a two-level approach to data extraction for comprehensive evaluation. First, for qualitative analysis, a slightly flexible criterion was applied, provided the studies used a topical formulation of spironolactone, regardless of the dose, study design, or clinical outcome parameters. The qualitative studies were then analysed narratively in this systematic review. For the second level, the quantitative meta-analysis, a stricter criterion was applied. The baseline characteristics of the included studies and participants were carefully extracted, including the author's first name, year of publication, the country where the study was conducted, sample size (n), mean age, gender, and study duration. The efficacy outcomes were measured by the total lesion count (TLC) from baseline at week 6 or 8, and the acne severity index (ASI) from baseline at week 6 or 8. Additionally, safety outcomes, such as side effects from the intervention and treatment dropout due to side effects, were described narratively without statistical analysis.

Sensitivity analysis Absent in the reviewed literature.

Language restriction No restrictions were applied regarding language during the search process.

Country(ies) involved United Kingdom.

Keywords Spironolactone; Acne vulgaris; Topical delivery; Lesions; Systematic review; Meta-analysis.

Contributions of each author

Author 1 - Saedah Dereiah - Methodology, formal analysis, investigation, resources, data curation.
Email: saedah.dereiah@hud.ac.uk
Author 2 - Muhammad Usman Ghori - Conceptualization, methodology, formal analysis, investigation, data curation, supervision.
Email: m.ghori@hud.ac.uk
Author 3 - Barbara R. Conway - Conceptualization, methodology, formal analysis, investigation, data curation, supervision. project administration.
Email: b.r.conway@hud.ac.uk