INPLASY

Impact of Topical Delgocitinib on Patient-Reported Outcomes in AD and CHE Compared With Placebo or Active Therapies: A Systematic Review. & Meta Analysis

INPLASY202590047

doi: 10.37766/inplasy2025.9.0047

Received: 12 September 2025

Published: 13 September 2025

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ADMINISTRATIVE INFORMATION

Support - N/A.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202590047

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 September 2025 and was last updated on 13 September 2025.

INTRODUCTION

Review question / Objective Does topical delgocitinib improve patient-reported outcomes (PROs) such as itch, pain, treatment satisfaction, and quality of life in patients with atopic dermatitis (AD) or chronic hand eczema (CHE) compared to vehicle or active comparators?

Rationale Although several randomized controlled trials (RCTs) have evaluated the clinical efficacy of delgocitinib, a systematic review and meta-analysis focusing specifically on patient-reported outcomes (PROs) has not yet been conducted. Given the high burden of AD and CHE on daily functioning and the emphasis on patient-centered care, synthesizing the available evidence on itch relief, quality of life, and treatment satisfaction can assist in guiding clinical decision-making and future research.

Condition being studied Atopic dermatitis (AD) and chronic hand eczema (CHE).

METHODS

Search strategy A structured search strategy combined controlled vocabulary (MeSH) and free-text terms related to delgocitinib, eczema, and patient-reported outcomes (PROs). A Boolean/phrases search strategy will be utilized with the following terms to refine the search: (delgocitinib OR JTE-052 OR pan-JAK inhibitor) AND (atopic dermatitis OR eczema OR chronic hand eczema or CHE) AND (quality of life OR patient reported OR PRO OR itch OR pruritic OR DLQ OR treatment satisfaction OR HRQoL OR pain). The search strategy was conducted with the assistance of the University Health Sciences Librarian.

Participant or population Pediatric or adult patients with clinically diagnosed atopic dermatitis

or chronic hand eczema, enrolled in randomized controlled trials of delgocitinib.

Intervention Topical delgocitinib (ointment or cream formulation, any strength or dosing schedule).

Comparator Vehicle/placebo or an active comparator (e.g., tacrolimus ointment, alitretinoin).

Study designs to be included Randomized controlled trials (parallel-group, double-blind, vehicle-controlled, or active-controlled).

Eligibility criteria Inclusion: RCTs evaluating topical delgocitinib in AD or CHE patients, reporting at least one PRO/HRQoL (itch, pain, DLQI, PaGA, treatment satisfaction).Exclusion: Non-RCT designs, preclinical/animal studies, studies without PROs, conference abstracts without full data, and non-English publications.

Information sources Electronic databases: PubMed, Scopus, EBSCOhost (MEDLINE, CINAHL, CENTRAL).
Trial registries: ClinicalTrials.gov.
Other: Reference lists of included studies.

Main outcome(s) Change in pruritus numerical rating scale (NRS) from baseline to end of blinded treatment.

Additional outcome(s)
- Dermatology Life Quality Index (DLQI) or other validated HRQoL instruments
- Patient's Global Assessment (PaGA) treatment success
- Pain NRS
- Sleep interference or treatment satisfaction scales.

Data management Study screening and data extraction will be performed independently by two reviewers using Covidence. Data will be extracted into a standardized form, with consensus or third-party adjudication for discrepancies.

Quality assessment / Risk of bias analysis Two reviewers will independently assess risk of bias using the Cochrane Risk of Bias 2 (RoB 2) tool across all five domains (randomization, deviations, missing data, measurement, reporting). Each study will be rated as low, some concerns, or high risk.

Strategy of data synthesis Separate meta-analyses will be performed for AD and CHE. Continuous outcomes (e.g., pruritus NRS, DLQI) will be synthesized as mean difference (MD) or standardized mean difference (SMD) with 95% confidence intervals. Dichotomous outcomes (e.g., PaGA success) will be analyzed as risk ratios (RRs). Random-effects models will be used as the default, with fixed-effect models in sensitivity analyses. Heterogeneity will be assessed using I^2 and Cochran's Q.

Subgroup analysis
Pre-specified subgroups include:
- Condition: AD vs CHE
- Age group: pediatric vs adult
- Formulation: ointment vs cream
- Comparator: vehicle vs active comparator.

Sensitivity analysis Analyses will explore fixed-effect versus random-effects modeling, and assess the influence of single trials through leave-one-out analyses for all studies and those at high risk of bias.

Language restriction Only English-language publications will be included.

Country(ies) involved United States (Sacred Heart University & Stamford Hospital, Connecticut).

Keywords Delgocitinib; JTE-052; pan-JAK inhibitor; atopic dermatitis; chronic hand eczema; patient-reported outcomes; quality of life; pruritus; Dermatology Life Quality Index; PaGA.

Dissemination plans The findings will be disseminated through peer-reviewed publication, presentation at dermatology and pharmacology conferences.

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