INPLASY

Associations of glucose- and lipid-lowering medications with incident psoriasis: a protocol for a systematic review of real-world observational studies

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Completed but not published.

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 19 July 2026 and was last updated on 19 July 2026.

INTRODUCTION

Review question / Objective Among individuals without known psoriasis at baseline, is the use of glucose-lowering or lipid-lowering medications, compared with active medications, mixed treatment groups, medication nonuse, or different levels of medication exposure, associated with the risk of incident or first-recorded psoriasis in longitudinal observational studies?

Condition being studied Psoriasis is a chronic immune-mediated inflammatory disease primarily affecting the skin and, in some patients, the joints and other organ systems. It is closely associated with obesity, diabetes, insulin resistance, dyslipidemia, and metabolic syndrome. This review focuses on incident or first-recorded psoriasis among individuals without known psoriasis at baseline or at the index date. It examines whether the use of glucose-lowering or lipid-lowering medications is associated with subsequent psoriasis risk. Studies reporting a composite outcome of psoriasis and psoriatic arthritis are considered as supporting evidence when psoriasis-specific results are unavailable.

METHODS

Participant or population ndividuals without known psoriasis at baseline or at the index date were eligible. Studies were also eligible when the original investigators explicitly evaluated incident or first-recorded psoriasis after medication exposure. The populations mainly included patients receiving treatment for diabetes, dyslipidemia, or related metabolic conditions in routine healthcare settings. Studies with insufficiently described baseline psoriasis exclusion were retained when the outcome was reported as incident or first-recorded psoriasis, but this limitation was considered in the risk-of-bias assessment and interpretation.

Intervention Use of an identifiable glucose-lowering or lipid-lowering medication. Eligible exposure definitions included medication initiation,

current or previous use, cumulative exposure, duration or frequency of use, treatment persistence, and medication adherence. Glucose-lowering medications included metformin, sulfonylureas, thiazolidinediones, dipeptidyl peptidase-4 inhibitors, glucagon-like peptide-1 receptor agonists, sodium-glucose cotransporter-2 inhibitors, alpha-glucosidase inhibitors, insulin, and other identifiable glucose-lowering agents. Lipid-lowering medications included statins, fibrates, and other identifiable lipid-lowering agents.

Comparator Eligible comparators included another active glucose-lowering or lipid-lowering medication, a mixed medication-treated population, nonuse of the target medication, no use of lipid-lowering medication, or a different level of medication exposure. Comparisons based on exposure duration, cumulative use, prescription frequency, treatment persistence, or medication adherence were also eligible. Active-comparator, mixed-comparator, medication-nonuser, and exposure-intensity comparisons were considered separately because they address different clinical questions.

Study designs to be included Longitudinal observational studies were eligible, including prospective or retrospective cohort studies, active-comparator new-user studies, target trial emulations, landmark cohort studies, case-control studies, and nested case-control studies. Cross-sectional and ecological studies were not eligible.

Eligibility criteria Studies were eligible if they evaluated an identifiable glucose-lowering or lipid-lowering medication in relation to incident or first-recorded psoriasis. Participants had to be free of known psoriasis at baseline or the index date, or the original study had to explicitly define psoriasis recorded after baseline as an incident outcome. Eligible comparators included active medications, mixed treatment populations, medication nonusers, and groups defined by exposure duration, frequency, cumulative use, persistence, or adherence. Psoriasis could be identified through clinical diagnoses, electronic health records, diagnostic codes, insurance claims, or a defined case-identification algorithm. Studies had to report an HR, OR, or RR with a 95% CI, or sufficient data for its calculation. Studies reporting only a composite psoriasis and psoriatic arthritis outcome were included as supporting evidence when psoriasis-specific results were unavailable. Cross-sectional studies, ecological studies, case reports, case series, animal or cellular studies, reviews, commentaries, editorials, and protocols were excluded. Studies limited to psoriasis severity or treatment response, studies without an identifiable medication, comparator, or incident outcome, and completely duplicate reports without additional information were also excluded. No language restrictions were applied.

Information sources PubMed, Embase, Web of Science Core Collection, and the Cochrane Library were searched from database inception to July 1, 2026. Controlled vocabulary and free-text terms for psoriasis were combined with terms for glucose-lowering and lipid-lowering medications, including relevant medication classes and individual drug names. Search terms were adapted to the indexing system and syntax of each database. No language restrictions were applied. Reference lists of included reports and relevant systematic reviews were also examined to identify additional eligible studies. Authors were not routinely contacted for unpublished data.

Main outcome(s) The primary outcome was incident or first-recorded psoriasis occurring after study baseline or the index date. Psoriasis could be identified using clinical diagnoses, electronic health records, International Classification of Diseases codes, insurance claims, or a defined case-identification algorithm. Outcome assessment began after the index date, with any lag period and follow-up duration recorded as defined in the original study. The effect measures of interest were adjusted hazard ratios, odds ratios, or risk ratios with corresponding 95% confidence intervals. When multiple outcome definitions were reported, the original study's primary outcome was selected; otherwise, the most psoriasis-specific, clinically restricted, or validated definition was prioritized. Composite outcomes combining psoriasis and psoriatic arthritis were treated as supporting outcomes rather than equivalent primary outcomes.

Quality assessment / Risk of bias analysis Two reviewers independently assessed the principal effect result selected from each included report using the Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool. The assessed domains were bias due to confounding, selection of participants, classification of interventions or exposures, deviations from intended interventions or exposures, missing data, measurement of outcomes, and selection of the reported result. Domain-level and overall judgments were classified as low, moderate, serious, critical, or no information. Overall judgments followed ROBINS-I guidance and were not based on numerical scores. Disagreements were resolved through discussion or, when necessary, adjudication by a third

reviewer. A separate GRADE assessment was not performed.

Strategy of data synthesis A structured narrative synthesis was conducted. Effect estimates were grouped by target medication, comparator category, and outcome type. Active-comparator, mixed or non-active comparator, medication-nonuser, treatment-strategy, and exposure-duration, intensity, or adherence comparisons were summarized separately. Study design, time zero, outcome definition, precision, risk of bias, and data source were considered when interpreting the results. Potential overlap between database populations was assessed, and reports addressing the same question using overlapping populations were not treated as independent replications. HRs, ORs, and RRs were retained in their originally reported forms. Meta-analysis was considered only for sufficiently comparable and independent studies. Because few independent studies were available within each medication–comparator–outcome group and substantial clinical and methodological differences remained, no pooled effect estimate was calculated. Forest plots displayed study-specific.

Subgroup analysis No pooled subgroup analysis was performed because no meta-analysis was undertaken. Evidence was stratified descriptively by medication class, comparator category, psoriasis-specific versus composite outcome, exposure timing, cumulative exposure, treatment persistence, medication adherence, and clinical subgroups reported by the original studies. Subgroup estimates were treated as supporting or exploratory evidence and were interpreted in relation to their comparator, study design, precision, and risk of bias. They were not used as the sole basis for medication-class conclusions.

Sensitivity analysis No review-level sensitivity meta-analysis was performed because quantitative pooling was not undertaken. Sensitivity analyses reported by the original studies were extracted and summarized separately. These included alternative outcome definitions, monotherapy restrictions, additional confounding adjustment, per-protocol analyses, different treatment-gap definitions, and alternative exposure or follow-up windows. Their consistency with the principal result was examined qualitatively. When a sensitivity analysis differed materially in population, comparator, time zero, exposure definition, outcome definition, or analytical strategy, the additional limitations were considered separately rather than assuming that the principal risk-of-bias assessment applied without qualification.

Language restriction No language restrictions will be applied.

Country(ies) involved China.

Keywords psoriasis; incident psoriasis; glucose-lowering medications; lipid-lowering medications; real-world data; observational studies; pharmacoepidemiology; systematic review.

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