INPLASY PROTOCOL

To cite: Zou et al. Risk of Herpes Zoster associated with biological therapies for psoriasis and psoriatic arthritis: A systematic review and meta-analysis. Inplasy protocol 202110027. doi: 10.37766/inplasy2021.1.0027

Received: 09 January 2021

Published: 10 January 2021

Corresponding author:
Ailing Zou

70289952@qq.com

Author Affiliation:
Huangshi Central Hospital, Affiliated Hospital of Hubei Polytechnic University, Edong Health Care Group, Huangshi, Hubei, China

Support: **None.**

Review Stage at time of this submission: **Data analysis.**

Conflicts of interest:
The authors declare no conflict of interest.

Risk of Herpes Zoster associated with biological therapies for psoriasis and psoriatic arthritis: A systematic review and meta-analysis

Zou, AL[1]; Chen, YJ[2]; Shi, N[3]; Ye, Y[4].

Review question / Objective: **To evaluate the risk of HZ in psoriasis and psoriatic arthritis patients treated with biological therapy. P: patients with psoriasis or psoriatic arthritis; I: biological therapies (adalimumab, etanercept, infliximab, alefacept, efalizumab, ustekinumab, etc.); C: non-biological therapies, non-biological systemic therapies, or controls; O: studies reporting the incidence of HZ in case and control groups; S: case-control, cohort, or cross-sectional studies.**
Condition being studied: **This study aimed evaluate the association between biologic drugs and HZ in psoriasis and psoriatic arthritis patients. We believe that our study makes a significant contribution to the literature because many scholars have claimed that biological drugs could offer the same safety as non-biological systemic therapies when administrated long term; others have shown that they increased the risk of infections.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 January 2021 and was last updated on 10 January 2021 (registration number INPLASY202110027).

INTRODUCTION

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METHODS

Participant or population: Inclusion criteria (1) Subjects: patients with psoriasis or psoriatic arthritis; (2) Interventions: biological therapies (adalimumab, etanercept, infliximab, alefacept, efalizumab, ustekinumab, etc.); (3) Comparators: non-biological therapies, non-biological systemic therapies, or controls; (4) Outcomes: studies reporting the incidence of HZ in case and control groups; and (5) Study design: case-control, cohort, or cross-sectional studies. Exclusion criteria (1) in vitro and or animal studies; (2) non-English articles; (3) studies that did not report cases of HZ infection; and (5) reviews, case reports, thesistheses, and or conference abstracts.

Intervention: Biological therapies (adalimumab, etanercept, infliximab, alefacept, efalizumab, ustekinumab, etc.

Comparator: Non-biological therapies, non-biological systemic therapies, or controls.

Study designs to be included: Case-control, cohort, or cross-sectional studies.

Eligibility criteria: Inclusion criteria (1) Subjects: patients with psoriasis or psoriatic arthritis; (2) Interventions: biological therapies (adalimumab, etanercept, infliximab, alefacept, efalizumab, ustekinumab, etc.); (3) Comparators: non-biological therapies, non-biological systemic therapies, or controls; (4) Outcomes: studies reporting the incidence of HZ in case and control groups; and (5) Study design: case-control, cohort, or cross-sectional studies. Exclusion criteria (1) in vitro and or animal studies; (2) non-English articles; (3) studies that did not report cases of HZ infection; and (5) reviews, case reports, thesistheses, and or conference abstracts.

Information sources: We searched for published articles in the following electronic databases: PubMed, Embase, and Web of Science, until 9 March, 2020; searches were limited to human studies and English-language publications. Search terms, as both keywords and subject headings, included ('adalimumab', 'etanercept', 'infliximab', 'golimumab', 'alefacept', 'efalizumab', 'rituximab', 'ustekinumab', ixekizumab', 'secukinumab','brodalumab', 'guselkumab', 'biological therapy') AND ('HZ', 'herpes zoster', 'shingles') AND ('psoriasis') OR ('psoriatic arthritis'). We also conducted a manual search by reviewing the reference lists of all included studies.

Main outcome(s): Biological therapies, especially TNF-α inhibitors, may contribute to the risk of Herpes Zoster in psoriasis and psoriatic arthritis patients. Amongst these agents, infliximab and etanercept have been shown to significantly increase the risk of HZ; younger age and female gender may also be risk factors.

Quality assessment / Risk of bias analysis: We independently assessed the quality of Randomized controlled trials (RCTs) and non-RCTs using the Cochrane risk of bias tool and the Newcastle-Ottawa scale, respectively. A score of 0–9 (marked as stars) was allocated to each study, except RCTs. RCTs and non-RCTs achieving five or more stars were considered to be of high quality.

Strategy of data synthesis: The following information was extracted from the included studies: first author's name, year of publication, study design, total number of subjects, general characteristics of patients (disease, age, and sex), treatment

duration, follow-up duration, number of patients in each treatment group or under per drug, and number of HZ cases in each treatment group or with per drug.

Subgroup analysis: Subgroup analyses were as performed by study design, mean age, and gender.

Sensibility analysis: Sensitivity analyses were performed for heterogeneity.

Language: English.

Country(ies) involved: China.

Keywords: Risk; Herpes zoster; Biological therapies therapy; Psoriasis; Psoriatic arthritis.

Contributions of each author:

Author 1 - Ailing Zou performed literature search and prepared the draft of the paper.
Email: 70289952@qq.com
Author 2 - Yongjun Chen participated in manuscript preparation and analyzed the data.
Email: 171703926@qq.com
Author 3 - Nian Shi developed the main idea, designed the work, and read the manuscript critically.
Email: 635653672@qq.com
Author 4 - Yu Ye developed the main idea, designed the work, and read the manuscript critically.
Email: 602950812@qq.com