INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Non-melanoma skin cancer risk in patients receiving biological therapy for common inflammatory diseases

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Review question / Objective: **To explore whether the increased risk of NMSC for patients treated with biologics caused by the disease itself, the biological treatments, or both.**
Condition being studied: **Non-melanoma skin cancer.**
Eligibility criteria: **(1) Studies on people with RA, IBD, or psoriasis, (2) treatment based on biologics, (3) the risk estimates and 95% CI of NMSC connected with biologics compared with those not receiving biologics.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 July 2021 and was last updated on 02 July 2021 (registration number INPLASY202170005).

INTRODUCTION

Review question / Objective: **To explore whether the increased risk of NMSC for patients treated with biologics caused by the disease itself, the biological treatments, or both.**

Condition being studied: **Non-melanoma skin cancer.**

METHODS

Participant or population: **Rheumatoid arthritis (RA), inflammatory bowel disease (IBD), and psoriasis patients.**

Intervention: **(1) Studies on people with RA, IBD, or psoriasis, (2) treatment based on biologics, (3) the risk estimates and 95% CI of NMSC connected with biologics**

compared with those not receiving biologics.

Comparator: Rheumatoid arthritis (RA), inflammatory bowel disease (IBD), and psoriasis patients treated/not treated with biologics.

Study designs to be included: Randomized clinical trials, cohort studies, and nested case-control studies.

Eligibility criteria: (1) Studies on people with RA, IBD, or psoriasis, (2) treatment based on biologics, (3) the risk estimates and 95% CI of NMSC connected with biologics compared with those not receiving biologics.

Information sources: PubMed, Web of Science, Medline, Embase, Cochrane Library. From their creation to May 2021.

Main outcome(s): The risk estimates and 95% CI of non-melanoma skin cancer The outcome is defined in the original articles and the pooled relative risks and 95% CI is calculated using Stata.

Quality assessment / Risk of bias analysis: Begg's and Egger's tests will be done to assess the publication bias. The Newcastle-Ottawa Quality Assessment Scale will be used to evaluate study selection, matching, and outcome of the included studies.

Strategy of data synthesis: All statistical analyses are going to use Stata statistical software, the metan package. Q test is going to be used to assess heterogeneity in outcomes across studies, and I^2 statistic is used to quantify it. An I^2 score of 50% or higher is considered to show significant heterogeneity. In anticipation of clinical heterogeneity, the random-effects model is performed, otherwise the fixed-effects is performed.

Subgroup analysis: Subgroup analysis is based on the types of NMSC, types of biological therapy, study quality, follow-up years, and sample size.

Sensitivity analysis: None.

Country(ies) involved: China.

Keywords: Non-melanoma skin cancer; Inflammatory bowel disease; Psoriasis; Rheumatoid arthritis; Biologics.

Contributions of each author:
Author 1 - Ruolin Liu.
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