# INPLASY PROTOCOL

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**Support:** **None.**

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**Conflicts of interest:**
**None declared.**

# A Systematic Review with Meta-analysis of Comparative Efficacy and Safety of Risankizumab and Ustekinumab for Psoriasis Treatment

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**Review question / Objective:** **This study aimed to examine the drug effectiveness and safety of Risankizumab and Ustekinumab for psoriasis treatment, so as to provide a reference for clinical decision-making.**
**Condition being studied:** **Psoriasis is a prevalent chronic inflammatory dermatosis with a high recurrence rate and is associated with abnormal autoimmunity. In 2014, WHO defined it as a chronic, noninfectious, painful, disfiguring, and disabling disease that can hardly be cured.**
**Eligibility criteria:** **The research subject or patients who meet the diagnostic criteria [15] of psoriasis and receive Ustekinumab or Risankizumab as an intervention, the primary outcomes included Psoriasis Area and Severity Index (PASI), a static Physician's Global Assessment (sPGA), quality of life, and Psoriasis severity scale (PSS). The secondary outcome is the adverse events (AEs), this study used a Randomized Controlled Trials (RCTs) design.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 July 2022 and was last updated on 05 July 2022 (registration number INPLASY202270021).

## INTRODUCTION

**Review question / Objective:** **This study aimed to examine the drug effectiveness and safety of Risankizumab and Ustekinumab for psoriasis treatment, so as to provide a reference for clinical decision-making.**

**Condition being studied:** **Psoriasis is a prevalent chronic inflammatory dermatosis with a high recurrence rate and is associated with abnormal autoimmunity. In 2014, WHO defined it as a chronic, noninfectious, painful, disfiguring, and disabling disease that can hardly be cured.**

## METHODS

**Participant or population:** The research subject or patients who meet the diagnostic criteria of psoriasis.

**Intervention:** The research patients receive Ustekinumab as an intervention.

**Comparator:** The research patients receive Risankizumab as an intervention.

**Study designs to be included:** Only randomized controlled trials (RCTs) will also be considered.

**Eligibility criteria:** The research subject or patients who meet the diagnostic criteria [15] of psoriasis and receive Ustekinumab or Risankizumab as an intervention, the primary outcomes included Psoriasis Area and Severity Index (PASI), a static Physician's Global Assessment (sPGA), quality of life, and Psoriasis severity scale (PSS). The secondary outcome is the adverse events (AEs), this study used a Randomized Controlled Trials (RCTs) design.

**Information sources:** Databases from different sources such as Embase, PubMed, Cochrane Library and Web of Science were obtained, from inception to March 1th, 2022.

**Main outcome(s):** The primary outcomes included Psoriasis Area and Severity Index (PASI), a static Physician's Global Assessment (sPGA), quality of life, and Psoriasis severity scale (PSS).

**Additional outcome(s):** The secondary outcome is the adverse events (AEs).

**Quality assessment / Risk of bias analysis:** In order to examine the risk of bias, the Cochrane risk of bias assessment tool was applied for every included RCT, which refers to the following aspects: randomizing sequence generation, allocation concealment, blinding for partients, intervention givers, and outcome measures, incomplete data, selective reporting, and other sources of bias. The assessment risk of bias for each aspect was categorized as low, high, or unclear.

**Strategy of data synthesis:** Data were pooled using Stata 15.0 software. The mean difference (MD) with 95% confidence interval (95% CI) was used as a pooled statistic for continuous data and the risk ratio (RR) with 95% CI was used for dichotomous data, with a p-value less than 0.05 being considered statistically significant. Q test ($p \geq 0.1$) and Chi-square test ($I2 \leq 50\%$) would indicate less possibility of heterogeneity, then the fixed-effect model would be applied for data synthesis, otherwise high probability of heterogeneity would be considered and a random-effect model should be applied, or the heterogeneity source would be identified via a subgroup analysis. Egger's test was used to assess publication bias in which $p>0.05$ indicated aa a low chance of publication bias.

**Subgroup analysis:** Subgroup Analysis was performed to explore the source and size of heterogeneity among studies when necessary.

**Sensitivity analysis:** Sensitivity analysis was performed to explore the source and size of heterogeneity among studies when necessary.

**Country(ies) involved:** China.

**Keywords:** Risankizumab, Ustekinumab, psoriasis, biological therapy,meta-analysis.

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