

INPLASY PROTOCOL

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Corresponding author:
Tsai Meng-Ko

raymondpaper@gmail.com

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None declared.

Risk for lower gastrointestinal perforation in rheumatoid arthritis treated with tocilizumab compared to TNF and other biologics: A systematic review and meta-analysis

Tsai, X¹; Chen, MY².

Review question / Objective: P (Rheumatoid Arthritis); I (Tocilizumab) C (other treatment);O(lower Gastrointestinal Perforation event rate).

Condition being studied: To evaluate gastrointestinal (GI) perforation in rheumatoid arthritis (RA) patients receiving tocilizumab, or other biologic agents.

Study designs to be included: observational study design.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 June 2023 and was last updated on 01 June 2023 (registration number INPLASY202360004).

INTRODUCTION

Review question / Objective: (Rheumatoid Arthritis); I (Tocilizumab) C (other treatment);O(lower Gastrointestinal Perforation event rate).

Condition being studied: To evaluate gastrointestinal (GI) perforation in rheumatoid arthritis (RA) patients receiving tocilizumab, or other biologic agents.

METHODS

Participant or population: Rheumatoid Arthritis.

Intervention: Rheumatoid Arthritis.

Comparator: Other treatment of biologic agents.

Study designs to be included: Observational study design.

Eligibility criteria: Rheumatoid Arthritis with Tocilizumab treatment.

Information sources: Information from theses and dissertations published by various academic institutions.

Main outcome(s): Lower Gastrointestinal Perforation event rate.

Quality assessment / Risk of bias analysis: In this study, the quality assessment was performed by two independent reviewers who evaluated the included studies based on predefined criteria provided by the Cochrane risk-of-bias tool, version 2. system. The reviewers assessed various aspects of study design, sample size, data collection methods, statistical analysis, and reporting of results.

The risk of bias analysis involved the identification and evaluation of potential sources of bias in each included study. The reviewers carefully examined the risk of bias across different domains, including selection bias, performance bias, detection bias, attrition bias, and reporting bias. They considered factors such as randomization, blinding, allocation concealment, follow-up, and selective outcome reporting.

Strategy of data synthesis: We will use CMA software to analysis the data. We will use event rate.

Subgroup analysis: Other treatment of biologic agents.

Sensitivity analysis: We first conducted this study, including all studies that met our initial inclusion criteria, and then repeated the analysis using more stringent criteria (e.g., only including studies with low risk of bias).

Country(ies) involved: Taiwan, no multi-national authors.

Keywords: Rheumatoid Arthritis, lower Gastrointestinal Perforation, Tocilizumab.

Contributions of each author:

Author 1 - Tsai, Meng-Ko - Design the study, Performing Statistical Software Analysis.

Email: raymondpaper@gmail.com

Author 2 - Chen Miao-Yi.

Email: raymondpaper@gmail.com

Author Affiliation: 1. Division of Rheumatology, Immunology and Allergy, Department of Internal Medicine, Tri-Service General Hospital, National Defense Medical Center, Taipei, Taiwan; 2. Division of Rheumatology, Immunology and Allergy, Department of Internal Medicine, Taichung Armed Forces General Hospital, Taichung, Taiwan.