

INPLASY PROTOCOL

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None declared.

Risk of Severe Infection in Patients with ANCA-Associated Vasculitis Treated with Rituximab: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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Review question / Objective: P (ANCA- Associated Vasculitis); I (Rituximab); C (other treatment of AAV); O(Severe Infection).

Condition being studied: ANCA-associated vasculitis (AAV) is a group of rare autoimmune diseases that cause inflammation and damage to blood vessels throughout the body. AAV is characterized by the presence of antineutrophil cytoplasmic antibodies (ANCA) in the blood, which are produced by the immune system and attack the body's own tissues. AAV can affect different organs and tissues, including the kidneys, lungs, skin, and nervous system, and can lead to a range of symptoms, such as fever, fatigue, weight loss, joint and muscle pain respiratory problems, and kidney dysfunction. The severity and course of AAV can vary widely between individuals, and prompt diagnosis and treatment are important to prevent serious complications and improve outcomes. Treatment often involves a combination of immunosuppressive drugs, such as corticosteroids and rituximab, and supportive care.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 May 2023 and was last updated on 10 May 2023 (registration number INPLASY202350037).

INTRODUCTION

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autoimmune diseases that cause inflammation and damage to blood vessels throughout the body. AAV is characterized by the presence of antineutrophil cytoplasmic antibodies (ANCA) in the blood, which are produced by the immune system and attack the body's own tissues. AAV can affect different organs and tissues, including the kidneys, lungs, skin, and

nervous system, and can lead to a range of symptoms, such as fever, fatigue, weight loss, joint and muscle pain respiratory problems, and kidney dysfunction. The severity and course of AAV can vary widely between individuals, and prompt diagnosis and treatment are important to prevent serious complications and improve outcomes. Treatment often involves a combination of immunosuppressive drugs, such as corticosteroids and rituximab, and supportive care.

METHODS

Search strategy: The following databases are used for the search: PubMed/MEDLINE, Embase, and Web of Science.

Participant or population: ANCA-Associated Vasculitis.

Intervention: Rituximab.

Comparator: Other treatment of AAV.

Study designs to be included: RCT.

Eligibility criteria: RCT of AAV treated with rituximab.

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

Main outcome(s): Serious infection risk.

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 risk ratio to.

Subgroup analysis: Induction therapy or maintenance therapy.

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.

Language restriction: limited to English publish.

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

Keywords: Rituximab, ANCA associated vasculitis, AAV.

Contributions of each author:

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