

SYSTEMATIC REVIEW

Efficacy of Ozoralizumab vs. Golimumab for Rheumatoid Arthritis: A Systematic Review

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ABSTRACT

Introduction: Rheumatoid arthritis, a systemic autoimmune disease, affects 13% of the world population. As a well-established therapy, golimumab provides a key benchmark for assessing novel biological treatments. In contrast, ozoralizumab represents an innovative therapeutic approach. This study aimed to comprehensively elucidate the efficacy of golimumab and ozoralizumab in reducing rheumatoid arthritis disease activity.

Methods: Literature searches were conducted throughout PubMed, Cochrane, and Web of Science using Boolean operators, covering available records from database inception until October 2024. The literature search was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The included studies were randomized controlled trials (RCT) evaluating the efficacy of ozoralizumab or golimumab for rheumatoid arthritis. Five studies from 2015 to 2022 were obtained and assessed using the Cochrane Risk of Bias 2 (ROB2) tool.

Results: The five studies consisted of two ozoralizumab trials and three golimumab trials conducted in Japan and the United States, involving 2,305 participants. All included studies exhibited a low risk of bias based on assessments undertaken using the ROB2 tool. The differences in Disease Activity Score-28 (DAS28) remission rates between ozoralizumab and placebo were 42.6% in one study and 6.3% in the other, whereas golimumab mainly showed smaller differences versus placebo across three studies (4.6%, 5.9%, and 10.4%).

Conclusion: This study demonstrates DAS28 remission in rheumatoid arthritis patients receiving either ozoralizumab or golimumab therapy. Nonetheless, further direct statistical studies are essential to determine which therapy is superior and under what circumstances it should be administered.

Keywords: Ozoralizumab; golimumab; rheumatoid arthritis; Disease Activity Score-28 (DAS28); disease-modifying antirheumatic drugs (DMARDs)

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Highlights:

1. This study provides robust evidence that establishes ozoralizumab as a novel tumor necrosis factor-alpha (TNF- α) inhibitor for rheumatoid arthritis.
2. According to the findings, ozoralizumab may be a clinician's choice due to its comparable efficacy and potential advantages over golimumab.

Article history: •Received 6 December 2024 •Revised 29 May 2025 •Accepted 14 July 2025 •Published 31 August 2025

INTRODUCTION

Rheumatoid arthritis brings about chronic and escalating inflammation, mainly to the synovial membrane of the joints. This medical condition prompts the immune system to target the joint tissues, causing harm that can be recognized by increased immune cells, including macrophages and T lymphocytes (Alivernini et al., 2019; Volkov et al., 2020; Patidar et al., 2022). The prevalence of rheumatoid arthritis has reached 13% of the total population worldwide, totaling approximately 2.4 million sufferers (World Health Organization, 2022). In Indonesia, the prevalence was estimated at 7.30%, with the majority of patients being female (Ministry of Health of the Republic of Indonesia, 2019).

Treatments for rheumatoid arthritis encompass non-pharmacological strategies, such as supportive counseling and rehabilitation, in addition to various drug therapies. Biologic disease-modifying anti-rheumatic drugs (bDMARDs), especially for patients who are unresponsive to conventional therapy, have shown promising results in reducing symptoms (Kerschbaumer et al., 2020; Hidayat et al., 2021). Golimumab, a type of bDMARDs, has been widely used in the treatment of rheumatoid arthritis due to its notable therapeutic efficacy. Clinical trials such as those investigating golimumab in active rheumatoid arthritis despite methotrexate therapy (GO-FORWARD) and its effects on participants with active axial spondyloarthritis (GO-AHEAD) have confirmed that the medication is highly effective as a tumor necrosis factor-alpha (TNF- α) inhibitor, leading to significant improvements in disease activity, physical function, and quality of life (Luttrupp et al., 2019). However, safety evaluations conducted by Emery et al. (2016) revealed that 94.5% of patients treated with golimumab reported adverse effects. Additionally, injection site reactions were observed in 11.9% of the patients. While injection site responses and respiratory infections are common, major adverse events—such as infections and malignancies—are rare. These findings align with the safety profiles of other tumor necrosis factor (TNF) inhibitors (Furst et al., 2022).

In contrast to golimumab, ozoralizumab represents one of the latest innovations in rheumatoid arthritis treatment and has been recognized as a next-generation anti-TNF antibody (Ishiwatari-Ogata et al., 2022). Phase III clinical trials have demonstrated the effectiveness of this 38 kDa trivalent NANOBODY[®] compound in inhibiting TNF- α , along with a long half-life and favorable pharmacokinetic properties when administered subcutaneously at four-week intervals (Takeuchi et al., 2022; Tanaka et al., 2023). Its efficacy and safety were evaluated in two pivotal trials: a randomized, open-label trial in active

rheumatoid arthritis patients without methotrexate co-administration (OHZORA) and a randomized, double-blind, placebo-controlled trial in patients with rheumatoid arthritis and an inadequate response to methotrexate (NATSUZORA) (Takeuchi, 2023). A drug safety trial on ozoralizumab reported that 72.1% of patients experienced adverse effects, with injection site reactions occurring in only 1.3% of cases (Tanaka et al., 2023).

Given its well-established efficacy and safety profile, golimumab serves as an important benchmark for evaluating new biological therapies in rheumatoid arthritis. New bDMARDs should be compared to golimumab to ensure non-inferiority or superior efficacy and safety, as well as practicality in clinical use, particularly with regard to dosing frequency and patient adherence (Shimizu et al., 2021). Assessments of therapeutic efficacy using the Disease Activity Score-28 (DAS28) are essential for determining treatment response and disease progression (Savitri et al., 2019; Nasir et al., 2022; Pisaniello et al., 2022). Further research is required to comprehensively elucidate the comparative efficacy and safety of golimumab and ozoralizumab in reducing rheumatoid arthritis disease activity. Therefore, this study specifically compared these two agents to identify a more effective therapeutic option for the treatment of rheumatoid arthritis, with particular attention to their potential advantages associated with reduced adverse effects.

METHODS

Research methodology for the systematic review

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines (Page et al., 2021). Literature searches were performed between September 2 and October 30, 2024, covering all records from database inception in PubMed, Cochrane, and Web of Science. Boolean operators, Medical Subject Headings (MeSH) terms, and additional synonyms were employed to organize keywords for the literature search as follows: ("Rheumatoid Arthritis" OR "RA") AND ("Ozoralizumab" OR "OZR" OR "ATN-103") OR ("Golimumab") AND ("DAS28"). The literature selected for this study adhered to the subsequent inclusion criteria: (1) studies administering ozoralizumab or golimumab combined with methotrexate to rheumatoid arthritis patients, with a placebo comparison; (2) research assessing the safety and efficacy of ozoralizumab or golimumab through DAS28 assessments; (3) research categorized as randomized controlled trials; (4) publications from the last ten years. The following description defined the exclusion criteria: (1) studies with titles and abstracts irrelevant to the

research topic; (2) studies utilizing duplicate data; (3) studies not available in free full text; (4) studies not published in English or Indonesian; or (5) studies presented in the form of conference abstracts, review articles, case series, or case reports.

The quality of the included literature was assessed utilizing the Cochrane Risk of Bias 2 (ROB2) tool, which evaluated five domains: (1) outcome measurement, (2) reported result selection, (3) missing outcome data, (4) randomization processes, and (5) deviation from the intended intervention (Chandler et al., 2016). Each component might exhibit three levels of possible bias: high risk, low risk, or some concern. The data extraction for this investigation was conducted utilizing Microsoft Excel for Windows, version 2505 (Microsoft Inc., Redmond, WA, USA, 2025). The protocol for this systematic review (ID: CRD42024584494) was registered with the International Prospective Register of Systematic Reviews (PROSPERO).

RESULTS

Results of the literature search

The systematic literature search, conducted using predefined keywords, initially yielded 280 records from the PubMed (n=17), Cochrane (n=161), and Web of Science (n=102) databases as of October 2024, as illustrated in the PRISMA flow diagram (Figure 1). After removing 96 duplicate records, 184 items underwent screening based on title and abstract review. This initial screening phase resulted in the exclusion of 125 irrelevant records. The remaining 59 potentially eligible items were subjected to full-text review, during which 39 publications were excluded due to unavailability. The 20 accessible full texts were then assessed, leading to further exclusions: 14 articles did not report outcomes in the form of DAS28 below 2.6, and one study did not incorporate methotrexate as part of the interventions. Consequently, five studies were selected for final inclusion in this systematic review, all of which examined the effect of ozoralizumab and golimumab therapies in reducing disease activity, as assessed by DAS28 below 2.6, in patients with rheumatoid arthritis. The assessment of literature quality, carried out using the Cochrane RoB2 tool, exhibited that all five included studies had a low risk of bias. Detailed results of the assessment are summarized in Figure 2.

Characteristics of the included studies

Among the five studies included in this systematic review, three were conducted in Japan (Tanaka et al., 2016; Takeuchi et al., 2022; Tanaka et al., 2023), while the other two were carried out in

different countries (Emery et al., 2016; Keystone et al., 2016). As shown in Table 1, all studies were categorized as randomized controlled clinical trials using a placebo with a double-blind method. This systematic review involved a total of 2,305 participants throughout the included studies. Three of the five studies (Emery et al., 2016; Takeuchi et al., 2022; Tanaka et al., 2023) reported mean ages ranging from 48.2 to 55.0 years. The only source mentioning that participants had to be at least 18 years old was Keystone et al. (2016). Tanaka et al. (2016) found that the participants' ages varied from 25 to 75 years.

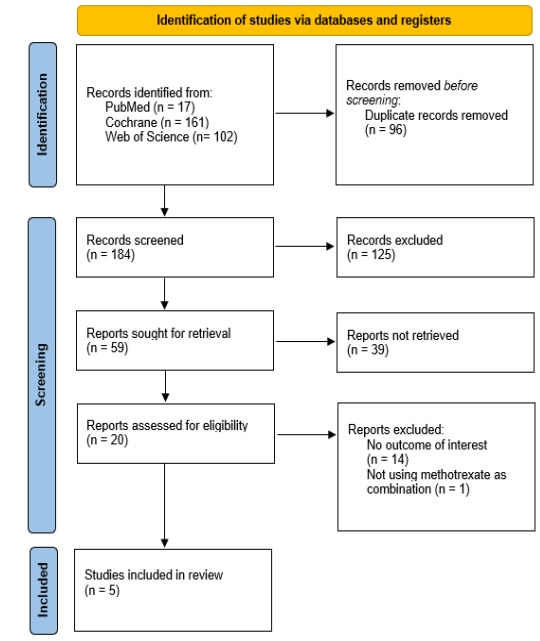


Figure 1. PRISMA flow diagram of the literature findings

	Randomization Process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall Bias	
(Takeuchi et al., 2022)	+	+	+	+	+	+	Low risk
(Tanaka et al., 2022)	+	+	+	+	+	+	Some concerns
(Tanaka et al., 2015)	+	+	+	+	+	+	High risk
(Keystone et al., 2016)	+	+	+	+	+	+	
(Emery et al., 2016)	+	+	+	+	+	+	

Figure 2. Assessment of the literature quality

Table 1. Characteristics of the research subjects

Author (year)	Country	Diagnosis criteria	RA duration	Total participants		Age (years)	DAS28 baseline		
				Female	Male		Placebo	Ozoralizumab	Golimumab
Takeuchi et al. (2022)	Japan	Fulfillment of ACR/EULAR 2010 categorization criteria for RA with insufficient response to MTX therapy	7.4±7.1 years	285	96	55.0±11.2	5.1±1.0	5.2±1.1	N/A
Tanaka et al. (2023)	Japan	Fulfillment of ACR/EULAR 2010 categorization criteria for RA with insufficient response to MTX therapy	7.4±7.1 years	285	96	55.0±11.2	5.78	5.17	N/A
Tanaka et al. (2016)	Japan	Adults diagnosed with RA according to the ACR 1987 revised criteria	≥3 months		269	20–75	N/A	N/A	N/A
Keystone et al. (2016)	USA	Patients diagnosed with RA based on the ACR 1987 revised criteria	≥3 months before screening		637	≥18	N/A	N/A	N/A
Emery et al. (2016)	N/A	Adults diagnosed with RA according to the ACR criteria	≥3 months prior to initiation of the study intervention	528	109	48.2±12.85	N/A	N/A	N/A

Notes: RA=rheumatoid arthritis; DAS28=Disease Activity Score-28; ACR= American Congress of Rheumatology; EULAR=European League Against Rheumatism; MTX=methotrexate; N/A=not available.

Two studies ([Takeuchi et al., 2022](#); [Tanaka et al., 2023](#)) determined that the average duration of rheumatoid arthritis among the patients was 7.4±7.1 years. All five included studies required the patients' rheumatoid arthritis to be active for at least three months prior to screening. [Tanaka et al. \(2016\)](#) and [Keystone et al. \(2016\)](#) were two studies that did not account for the sex of the participants. Two investigations ([Takeuchi et al., 2022](#); [Tanaka et al., 2023](#)) employed the American Congress of Rheumatology/European League Against Rheumatism (ACR/EULAR) 2010 criteria for the diagnosis of rheumatoid arthritis. In the remaining three studies, rheumatoid arthritis was diagnosed using the American Congress of Rheumatology (ACR) criteria ([Emery et al., 2016](#); [Keystone et al., 2016](#); [Tanaka et al., 2016](#)).

[Tanaka et al. \(2016\)](#) and [Keystone et al. \(2016\)](#) were among the five studies that

indicated methotrexate therapy was given at different doses before baseline measurement. In a different study, [Emery et al. \(2016\)](#) discovered that individuals who had not taken oral methotrexate for rheumatoid arthritis for more than three weeks prior to DAS28 baseline measurement were ineligible for treatment. The DAS28 baseline was only mentioned in the ozoralizumab studies. [Takeuchi et al. \(2022\)](#) reported a baseline of 5.1±1.0 for the placebo group and 5.2±1.1 for the ozoralizumab group. Meanwhile, [Tanaka et al. \(2023\)](#) found a baseline of 5.78 for the placebo group and 5.17 for the ozoralizumab group. The details are enumerated in Table 2.

The study by [Emery et al. \(2016\)](#) involving four groups of 637 methotrexate-naïve adult patients with active rheumatoid arthritis (GO-BEFORE) revealed no statistically significant differences in the American College of Rheumatology

Table 2. Characteristics of the research interventions

Author (year)	Duration of administration	Dosage and frequency of administration
Takeuchi et al. (2022)	24 weeks	RA patients were arbitrarily distributed in a 2:2:1 ratio to receive subcutaneous ozoralizumab (30 mg or 80 mg) or placebo every four weeks under double-blind conditions, with concomitant MTX therapy.
Tanaka et al. (2023)	52 weeks	RA patients were randomized in a 1:2:2 ratio to receive placebo + MTX (Group 1), ozoralizumab 30 mg + MTX (Group 2), and ozoralizumab 80 mg + MTX (Group 3). Patients administered a placebo (Group 1) for 24 weeks during Period A (double-blind phase) were then re-randomized in a 1:1 ratio to receive either ozoralizumab 30 mg (Group P/30 mg) or 80 mg (Group P/80 mg) for an additional 28 weeks in Period B (open-label phase).
Tanaka et al. (2016)	156 weeks	Patients with active RA were randomly assigned in a 1:1:1 ratio to receive subcutaneous placebo + MTX (group 1), golimumab 50 mg + MTX (group 2), or golimumab 100 mg + MTX (group 3) every four weeks.
Keystone et al. (2016)	256 weeks	Patients with active RA despite of MTX treatment were randomly allocated to receive placebo + MTX (group 1), golimumab 100 mg + placebo (group 2), golimumab 50 mg + MTX (group 3), or golimumab 100 mg + MTX (group 4) every four weeks.
Emery et al. (2016)	252 weeks	Patients with active RA were arbitrarily allocated to receive subcutaneous injections of placebo + MTX (group 1), golimumab 100 mg + placebo (group 2), golimumab 50 mg + MTX (group 3), or golimumab 100 mg + MTX (group 4) every four weeks.

Notes: RA=rheumatoid arthritis; MTX=methotrexate.

criteria for 50% response (ACR50). The four groups were administered placebo + methotrexate (group 1), golimumab 50 mg + methotrexate (group 2), golimumab 100 mg + methotrexate (group 3), and golimumab 100 mg + methotrexate (group 4). The combination of golimumab and methotrexate proved to be more effective than golimumab alone. Golimumab demonstrated a number of potential adverse effects, including gastrointestinal problems, infections, infestations, and abnormalities affecting the muscles, connective tissues, and bones. Pneumonia, pulmonary tuberculosis, and an increased risk of cancer (including uterine leiomyoma, basal cell carcinoma, non-small cell lung cancer, and breast cancer) are among the most prevalent and severe side effects (Emery et al., 2016).

Differences in the efficacy of ozoralizumab and golimumab as evidenced by DAS28 <2.6

Table 3 summarizes the outcomes of research interventions administered across the five analyzed studies. Figure 3 compares remission rates between ozoralizumab and placebo groups in rheumatoid arthritis patients, as evidenced by a DAS28 score below 2.6. Takeuchi et al. (2022) reported that 55.9% of patients treated with ozoralizumab achieved DAS28 remission, compared to only 13.3% in the placebo group. In contrast, according to the criteria set forth by Tanaka et al. (2023), the proportions of patients who attained remission were

63.6% for the placebo group and 69.9% for the ozoralizumab group.

Table 3. Outcomes of the research interventions

Author (year)	Groups	DAS28 <2.6
Takeuchi et al. (2022)	Placebo + MTX	13.3%
	Ozoralizumab + MTX	55.9%
Tanaka et al. (2023)	Placebo + MTX	63.6%
	Ozoralizumab + MTX	69.9%
Tanaka et al. (2016)	Placebo + MTX	55.9%
	Golimumab + MTX	61.8%
Keystone et al. (2016)	Placebo + MTX	32.3%
	Golimumab + MTX	42.7%
Emery et al. (2016)	Placebo + MTX	41.9%
	Golimumab + MTX	46.5%

Notes: DAS28=Disease Activity Score-28; MTX=methotrexate.

Figure 4 exhibits the proportions of patients who attained remission from rheumatoid arthritis, indicated by a DAS28 score under 2.6, across the analyzed golimumab studies. Tanaka et al. (2016) reported that 55.9% of patients in the placebo group and 61.8% in the golimumab group achieved remission after receiving interventions. Lower proportions of patients who attained remission were observed in the research by Keystone et al. (2016),

comprising 32.3% in the placebo group and 42.7% in the golimumab group. Similarly, [Emery et al. \(2016\)](#) discovered remission in 41.9% of patients who received placebo, compared to 46.5% in the golimumab group. All of the included studies administered golimumab or placebo as interventions in combination with methotrexate.

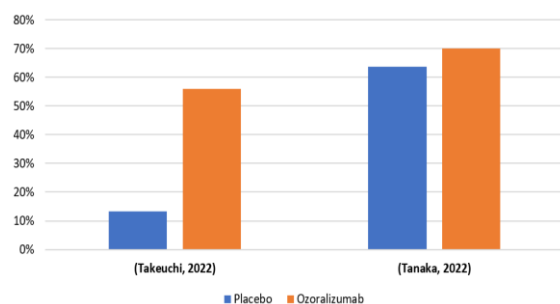


Figure 3. Remission rates (DAS28 <2.6) in the placebo vs. ozoralizumab groups

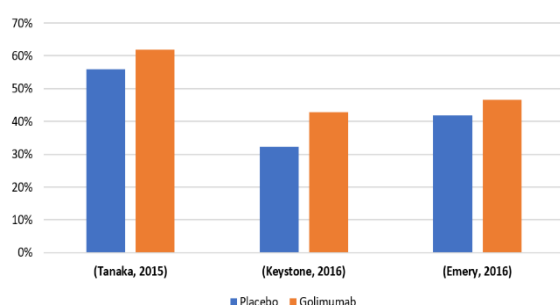


Figure 4. Remission rates (DAS28 <2.6) in the placebo vs. golimumab groups

DISCUSSION

This systematic review included five randomized controlled trials published between 2015 and 2022. Three investigations were conducted in Japan, one in the United States, and one did not specify the study location. The interventions varied across trials, including differences in drug combinations, doses, and treatment durations.

The majority of participants in the included studies were female, consistent with the well-documented sex disparity in autoimmune disorders such as rheumatoid arthritis ([World Health Organization, 2022](#)). Several mechanisms may underlie this predisposition, such as hormones, X chromosome-related factors, microchimerism, environmental variables, and microbiome alterations ([Kronzer et al., 2021](#)). One notion posits that estrogen may have a role as a key modulator of autoimmune responses. Specifically, estrogen

regulates micro ribonucleic acid (miRNA) expression in both lymphoid and non-lymphoid cells, influencing inflammatory pathways. The modulation of pro-inflammatory and autoimmune processes by estrogen is aided by its expression and estradiol-regulated messenger ribonucleic acids (mRNAs), which are known as protein-coding genes ([Lahita, 2023](#)).

Inclusion of participants in the trials was contingent upon the application of either the ACR 1987 criteria or the ACR/EULAR 2010 criteria for rheumatoid arthritis diagnosis. The ACR 1987 criteria are quite specific (76%) but demonstrate limited sensitivity (80%). The updated standard is the ACR/EULAR 2010 criteria, which exhibits higher sensitivity (97%) but far less specificity (55%) compared to the prior ACR 1987 criteria. The goal of these new criteria is to aid in the early classification of rheumatoid arthritis patients in order to prevent diagnostic delays ([Erickson et al., 2017](#)).

Across the five analyzed studies, two reported a disease duration of 7.4 ± 7.1 years among patients with rheumatoid arthritis ([Takeuchi et al., 2022](#); [Tanaka et al., 2023](#)). The other three studies revealed a disease duration of more than three months after initial screening. Disease duration is an important prognostic factor, as longer rheumatoid arthritis duration is associated with higher disease activity scores ([Tipsing & Sawanyawisuth, 2021](#)). All included trials required patients to take a continuous dosage of methotrexate for a minimum of four weeks before the administration of the intervention drug (golimumab or ozoralizumab). Additionally, the intervention groups in each trial comprised several combinations, including placebo, methotrexate, golimumab 50 mg, golimumab 100 mg, ozoralizumab 30 mg, and ozoralizumab 80 mg. The DAS28 baselines were only reported in the ozoralizumab studies. [Takeuchi et al. \(2022\)](#) documented mean scores of 5.1 ± 1.0 for the placebo group and 5.2 ± 1.1 for the ozoralizumab group. Meanwhile, [Tanaka et al. \(2023\)](#) reported mean scores of 5.78 for the placebo group and 5.17 for the ozoralizumab group.

Ozoralizumab is a novel rheumatoid arthritis medication that inhibits tumor necrosis factor alpha (TNF- α), designed to extend its plasma half-life by binding to human serum albumin. It exerts therapeutic effects by neutralizing both the membrane-bound and secreted versions of TNF- α . Clinical studies conducted by [Takeuchi et al. \(2022\)](#) and [Oyama et al. \(2022\)](#) reported a peak plasma concentration at six days post-administration and a half-life of 18 days. The safety profile was favorable, with mild-to-moderate infections being the most common side effects, whereas serious adverse reactions were uncommon.

On the other side, golimumab is a monoclonal antibody produced via recombinant deoxyribo-

nucleic acid (DNA) technology that mimics human immunoglobulin G, subclass 1, κ light chain (IgG1 κ) and primarily blocks TNF- α to prevent inflammation and joint damage in rheumatoid arthritis (Pelechas et al., 2019). Placebo-controlled trials demonstrated its efficacy for rheumatoid arthritis patients, indicated by significant improvements in C-reactive protein (CRP) levels, alongside reductions in interleukin-6 (IL-6), intercellular adhesion molecule 1 (ICAM-1), matrix metalloproteinase-3 (MMP-3), vascular endothelial growth factor (VEGF), and TNF levels (Pelechas et al., 2019; Purwaningsari et al., 2020). Golimumab reaches steady-state concentrations within 12 weeks, with peak serum levels occurring two to six days after a 50 mg subcutaneous injection. In patients with rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis, the steady-state trough concentrations were approximately 30% higher when administered with methotrexate compared to those not receiving the concomitant drug (Harzallah et al., 2017).

This systematic review found that both ozoralizumab and golimumab improved DAS28 remission rates in rheumatoid arthritis patients compared to placebo. In the study by Takeuchi et al. (2022), ozoralizumab administration led to a difference of 42.6% in DAS28 remission rates between the placebo and ozoralizumab groups. Furthermore, the statistical analysis indicated a significantly higher remission rate in the ozoralizumab group ($p < 0.001$). However, Tanaka et al. (2023) reported a smaller difference (6.3%) between the placebo-ozoralizumab group and the ozoralizumab group, possibly attributable to the therapeutic effect of the combined intervention. Notably, the other included studies did not provide statistical significance analysis of the differences between groups.

Consistent with the findings of the ozoralizumab studies, all three golimumab studies demonstrated higher DAS28 remission rates in the treatment groups versus placebo. The differences between the placebo and golimumab groups varied from 4.6% (Emery et al., 2016) to 10.4% (Keystone et al., 2016), with Tanaka et al. (2016) reporting an intermediate disparity of 5.9%. This disparity may reflect variations in study designs, particularly the crossover mechanism that allowed the transition from placebo to ozoralizumab or golimumab intervention after a certain week of treatment, potentially diminishing differences in the observed treatment effects. These findings position ozoralizumab as a promising bDMARD with sufficient efficacy comparable to golimumab, an established therapy supported by clinical guidelines and widely used in practice (Hidayat et al., 2021). The consistent differences between groups across studies, despite methodological variations, underscore its potential as a viable therapeutic

alternative for rheumatoid arthritis.

This systematic review offers a rigorous analysis of ozoralizumab, a novel trivalent nanobody that inhibits TNF- α , with particular focus on its efficacy and safety profile compared to golimumab, a fully human monoclonal antibody used as conventional therapy for rheumatoid arthritis. A key strength of this study lies in its exclusive focus on randomized controlled trials, ensuring the analysis was based on high-quality clinical evidence. By synthesizing data from five eligible trials, this systematic review provides practitioners with valuable insights into the potential of ozoralizumab as an additional option to established therapies, thereby improving decision-making related to rheumatoid arthritis treatment.

This study is subject to several limitations, the most significant being the absence of direct comparative trials with statistical analyses, which prevents definitive conclusions about the relative effectiveness of ozoralizumab versus golimumab in reducing DAS28 scores. Furthermore, the evidence base for ozoralizumab remains limited, with only two published randomized controlled trials available, in contrast to the more extensive and robust data on golimumab that support its well-established clinical profile. This disparity highlights the need for further phase III trials to confirm the therapeutic efficacy of ozoralizumab and clarify its role in current treatment protocols. Despite these constraints, the available data suggest that ozoralizumab exhibits efficacy comparable to golimumab, underscoring its promise as a therapeutic option arising from recent advancements in biologic therapy for rheumatoid arthritis.

CONCLUSION

The findings of this systematic review suggest that both ozoralizumab and golimumab exhibit substantial efficacy, as evidenced by reduced disease activity in patients with rheumatoid arthritis. However, direct comparative statistical analyses are essential to establish the relative superiority of these agents and to delineate the specific clinical contexts in which each may be optimally utilized. To strengthen the evidence base for ozoralizumab, future phase III clinical trials should incorporate long-term efficacy endpoints—such as radiographic progression and sustained remission—alongside thorough safety assessments, including immunogenicity and adverse event profiles across diverse patient populations. Moreover, the inclusion of patient-reported outcomes, quality of life measures, and direct head-to-head comparisons with established biologic therapies will be essential for fully elucidating the therapeutic value of ozoralizumab and clarifying its role within the existing rheumatoid arthritis treatment paradigm.

ACKNOWLEDGEMENT

The authors express gratitude to their peers from the Medical Study Program at the Faculty of Medicine, Universitas Airlangga, Surabaya, Indonesia, and to Fan Maitri Aldian for assistance with data analysis.

CONFLICT OF INTEREST

None.

FUNDING DISCLOSURE

None.

AUTHOR CONTRIBUTION

NE contributed to the conceptualization and design, in addition to collecting, analyzing, and interpreting the data, and drafting the article. KH collected the data, performed data analysis and interpretation, and provided statistical expertise. LR also collected the data, in addition to performing data analysis and interpretation. AM and LD performed critical revisions of the article for important intellectual content and finalized the report. CD also performed critical revisions of the article for important intellectual content and finalized the report, on top of providing statistical expertise.

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