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Comparative efficacy and safety of different recommended doses of telitacicept in patients with systemic lupus erythematosus in China: A systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Data extraction.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 April 2024 and was last updated on 20 December 2024.

INTRODUCTION

Review question / Objective Telitacicept, a new biological agent, was approved in China for treating systemic lupus erythematosus (SLE) in 2021. Its optimal dosing for treating SLE remains unclear. Therefore, the aim of this meta-analysis is to evaluate the efficacy and safety of various telitacicept doses in SLE treatment.

Rationale B lymphocyte play a predominant role in the adaptive immune response of SLE, which contributes to the generation of autoantibodies, presentation of autoantigens, and activation of autoreactive T cells, becoming an attractive candidate therapeutic target.

Condition being studied In March 2021, telitacicept was conditionally approved the Chinese National Medical Products Administration for the treatment of patients with active SLE in China. The purpose of this article is to study the therapeutic effect of different concentrations of Telitacicept on SLE through systematic review and meta-analysis to provide scientific basis for the treatment of SLE.

METHODS

Search strategy A comprehensive search was conducted across multiple databases, including PubMed, EMBASE, Cochrane libraries, Web of Science, China National Knowledge Infrastructure (CNKI), VIP, Wanfang, and Sinomed up to April 30, 2024. The search utilized a combination of keywords and index terms related to telitacicept and SLE. Moreover, all the screened and included articles in English or Chinese.

Participant or population All participants in the included studies were diagnosed with active SLE. Detailly, SLE patients aged 18 to 65 years who met the 1997 American College of Rheumatology criteria for SLE and receive stable standard therapy with positive ANA and/or anti-dsDNA and a SELENA-SLEDAI score ≥8.

Intervention SLE patients treated with telitacicept alone or in combination with standard regimens.

Comparator SLE patients were treated with placebo or other immunosuppressive drugs.

Study designs to be included (1) Inclusion of randomized controlled trials (RCTs) that evaluate the efficacy and safety of telitacicept in patients with SLE. These studies provide the most robust evidence for assessing treatment outcomes.
(2) Focus on patients diagnosed with SLE.

Eligibility criteria (1) Lack of control group to ensure that the efficacy of telitacicept can be compared against a standard of care or placebo.
(2) Review articles as they do not contain original data and are not primary sources of evidence.
(3) No related outcomes to maintain the focus and relevance of our systematic review and meta-analysis.
(4) Duplicate publications to avoid redundancy in data analysis and to ensure the integrity of our findings.
(5) Ongoing trials to ensure that only studies with complete data and final outcomes are included in our analysis.
(6) Unpublished material including non-peer-reviewed articles to ensure that all included studies have undergone rigorous peer review and meet the standards of scientific credibility.

Information sources We searched eight databases: PubMed, EMBASE, Cochrane libraries, Web of science, China National Knowledge Infrastructure (CNKI), VIP, Wanfang, and Sinomed etc.

Main outcome(s) The primary endpoint is the SLE Responder Index 4 (SRI 4), the secondary outcomes are adverse events and serious adverse events etc.

Additional outcome(s) A reduction of ≥ 4 points in SELENA-SLE Disease Activity Index (SELENA-SLEDAI) score, no worsening in Physician Global Assessment (PGA) score, No new 1A/1B British Isles Lupus Assessment Group (BILAG) domain etc.

Data management Two independent researchers (Shenglan Gao and Chunlong Yang) will screen all candidate articles based on titles and abstracts according to the inclusion/exclusion criteria, and then retrieve the full text of each potentially relevant trial for further evaluation. Differences of opinion will be resolved by a third independent critic.

Quality assessment / Risk of bias analysis The risk of bias in the included RCTs was appraised using the Cochrane Collaboration's "risk of bias" tool, following the guidelines outlined in the Cochrane manual version 5.1.0. This evaluation encompassed key aspects such as the generation of random sequences, concealment of allocation, implementation of blinding, handling of incomplete data, and the integrity of reported results, as well as the potential for other biases. The studies were categorized into "high," "unclear," or "low" risk of bias.

Strategy of data synthesis Meta-analysis was performed using Review Manager 5.4. We conducted analyses for alterations in different doses of telitacicept vs control conditions according to comparative studies. We determined the weighted mean difference (WMD) and 95% CIs for the impact of different concentrations of telitacicept on the efficacy and safety of the SLE patient vs the control group. Dichotomous data will be expressed as risk ratio (RR), with their 95% confidence intervals (CIs). RR is the ratio of the probability of an event occurring in the treatment group to the probability of the event occurring in a control group. Chi-square test and I2 statistic will be used to measure statistical heterogeneity. According to this suggestion by Tufanaru et al19. that the fixed-effects model should be used for a meta-analysis when the number of the included studies is less than five, therefore the pooled RRs for primary endpoint and secondary endpoints used the fixed-effects in this report.

Subgroup analysis Subgroup analysis were done based on the different dose of telitacicept.

Sensitivity analysis Not applicable.

Language restriction English or Chinese.

Country(ies) involved China.

Keywords Telitacicept, systemic lupus erythematosus, efficacy, safety.

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