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INPLASY

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

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ADMINISTRATIVE INFORMATION

Support - No.

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 12 July 2024.

INTRODUCTION

Review question / Objective To evaluate the efficacy and safety of different doses of telitacicept in the treatment of SLE patients.

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 The key words (((telitacicept) OR (RC18)) OR (RCT-18)) AND (((((((Lupus Erythematosus, Systemic[MeSH Terms])) OR (Systemic Lupus Erythematosus[Title/Abstract])) OR (Lupus Erythematosus Disseminatus[Title/Abstract])) OR (Libman-Sacks Disease[Title/Abstract])) OR (Disease, Libman-Sacks[Title/Abstract])) OR (Libman Sacks Disease[Title/Abstract])) are used for searching the controlled trials.

Participant or population People with Systemic lupus erythematosus (as diagnosed by a clinician or using any recognized diagnostic criteria) will be included.

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 Randomized controlled trials (RCTs) and cohort studies.

Eligibility criteria Included RCTs and cohort studies had to report on the related outcome about effecy and safet in SLE patients.

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 will be independently appraised by 2 researchers using the "risk of bias" tool of the Cochrane Collaboration and each included study will be evaluated for quality and risk of bias in accordance with Cochrane manual 5.1.0. The following criteria will be assessed: random sequence generation; allocation concealment; blinding; incomplete data; selected reporting the results; and other bias. The risk of bias will be classified as "high," "unclear," or "low." For observational studies, we utilized the Newcastle-Ottawa Scale for assessing the risk of bias. This scale encompasses 8 items within 3 domains including patient selection, comparability, and outcome assessment. For each numbered item under patient selection and outcome assessment, a study may be given a maximum of 1 star, whereas for comparability, a maximum of two stars can be awarded, and the overall scores varied between 0 to 9 points.

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 and Chinese.

Country(ies) involved China.

Keywords Telitacicept, systemic lupus erythematosus, efficacy, safety.

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