INPLASY

The efficacy and safety of anti- B-cell activating factor therapy drugs in the treatment of Systemic Lupus Erythematosus (SLE): 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.

INPLASY registration number: INPLASY202440101

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 25 April 2024.

INTRODUCTION

Review question / Objective To evaluate To evaluate the efficacy and safety of anti- B-cell activating factor therapy drugs (Belimumab, Blisibimod, Tabalumab, Atacicept and Telitacicept) in the treatment of systemic lupus erythematosus.

Condition being studied 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. The interaction between BAFF and its receptors including AFF-receptor (BAFF-R), transmembrane activator and calcium-modulator and cyclophilin ligand interactor (TACI) and B cell maturation antigen (BCMA), is critically involved in B cell maturation and plasma cell survival. anti-B-cell activating factor therapy drugs show great clinical potential.

METHODS

Participant or population SLE patients.

Intervention The patients in the experimental group were treated with Belimumab, Blisibimod, Tabalumab, Atacicept and Telitacicept alone or in combination with standard regimens.

Comparator The patients in the control group were treated with placebo or other immunosuppressivedrugs.

Study designs to be included Randomized controlled trials.

Eligibility criteria (1) Non-RCTs(2) No related outcomes and adverse effects(3) Lack of data(4) Repeated publications (non first line)(5) Literatures with insufficient text.

Information sources PubMed, EMBASE, Cochrane libraries, Web of science, China National

Knowledge Infrastructure (CNKI), VIP, Wanfang, and Sinomed.

Main outcome(s) SLE Responder Index 4 (SRI 4) and adverse events.

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

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."

Strategy of data synthesis Meta-analysis was performed using Review Manager 5.4. 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. When P50%, substantial heterogeneity will be considered to exist, and the random effects model will be applied to estimate the summary RR and 95% CI, otherwise a fixed effects model will be applied.

Subgroup analysis Subgroup analysis according to the drugs.

Sensitivity analysis No.

Language restriction English and Chinese.

Country(ies) involved China.

Keywords B-cell activating factor, systemic lupus erythematosus, efficacy, safety.

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