INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Evaluation of anifrolumab safety in systemic lupus erythematosus: A meta-analysis and systematic review

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Review question / Objective: **This study aimed to evaluate the safety of anifrolumab in patients with moderate-severe SLE.**
Eligibility criteria: **1) the study was designed as an RCT comparing anifrolumab with placebo for the treatment of active systemic lupus erythematosus. 2) Meanwhile, we excluded studies that i) were noncomparative, nonrandomized (such as case–control, cohort or cross-sectional) and were not written in English; ii) were original articles that could not provide valid data, were incomplete or had incomplete final data; iii) were animal experiments; and iv) were systematic reviews, systematic reviews, guidelines, conference abstracts, or experience reports.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 March 2022 and was last updated on 13 March 2022 (registration number INPLASY202230054).

INTRODUCTION

Review question / Objective: **This study aimed to evaluate the safety of anifrolumab in patients with moderate-severe SLE.**

Rationale: **Anifrolumab is a novel strategy for the treatment of systemic lupus erythematosus that antagonizes the activity of all type 1 interferons by binding to subunit 1 of the type I interferon receptor.**

Condition being studied: **At present, there are several RCTs about anifrolumab in the treatment of SLE.**

METHODS

Participant or population: systemic lupus erythematosus patients.

Intervention: Anifrolumab (intravenous or subcutaneous).

Comparator: Placebo.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: 1) the study was designed as an RCT comparing anifrolumab with placebo for the treatment of active systemic lupus erythematosus. 2) Meanwhile, we excluded studies that i) were noncomparative, nonrandomized (such as case–control, cohort or cross-sectional) and were not written in English; ii) were original articles that could not provide valid data, were incomplete or had incomplete final data; iii) were animal experiments; and iv) were systematic reviews, systematic reviews, guidelines, conference abstracts, or experience reports.

Information sources: The data were obtained from PubMed, Cochrane, Web of Science, and EMBASE.

Main outcome(s): Serious AEs were less common in the anifrolumab group than in the placebo group. The most common AEs included upper respiratory tract infection, nasopharyngitis , bronchitis , and herpes zoster.

Quality assessment / Risk of bias analysis: The studies were classified as having a low risk of bias, which means there is confidence that the results represent true treatment and adverse effects. The findings are likely to be reliable, as there are no primary or secondary sources of bias that could have influenced our results, supporting our conclusions with evidence

Strategy of data synthesis: Statistical analysis was performed using Review Manager (RevMan) version 5.4 software (Nordice Cochrane Center, Cochrane Collaboration, Copenhagen, Denmark, 2020). P0.10, I2 ≤50%), the fixed effect model was used. Otherwise, a random-effects model was selected for analysis. Subgroup analyses were performed according to adverse events.

Subgroup analysis: The clinical benefit of anifrolumab at a dose of 300 mg was the best available, whether administered subcutaneously or intravenously, and the incidence of serious AEs associated with anifrolumab is rare.

Sensitivity analysis: Not applicable.

Country(ies) involved: China.

Keywords: Systemic lupus erythematosus, type I interferon, anifrolumab, RCTs, meta-analysis.

Contributions of each author:
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