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INPLASY

The efficiency of low-dose interleukin-2 treatment in patients with systemic lupus erythematosus: A meta-analysis

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ADMINISTRATIVE INFORMATION

Support - Not applicable.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202380094

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 August 2023 and was last updated on 22 August 2023.

INTRODUCTION

Review question / Objective P:patients with systemic lupus erythematosus treated with or without low dose IL-2; I: low dose IL-2; C:the difference of clinical manifestations,laboratory test results to evaluate disease activity and change of lymphocyte subsets between patients with systemic lupus erythematosus treated with or without low dose IL-2; O:Clinical manifestations,laboratory test results to evaluate disease activity and change of lymphocyte subsets.

Condition being studied we performed a meta-analysis of reports documenting the efficiency of low dose IL-2 to treat SLE and the rate of adverse events in patients with SLE before and after the administration of ld IL-2 to better understand its effect and safety in SLE treatment.

METHODS

Participant or population Patients with systemic lupus erythematosus treated with or with out low dose IL-2.

Intervention Low dose IL-2.

Comparator The difference of clinical manifestations,laboratory test results to evaluate disease activity and change of lymphocyte subsets between patients with systemic lupus erythematosus treated with or without low dose IL-2.

Study designs to be included The inclusion criteria were (1) studies reporting outcome measures that included clinical indexes and lymphocyte subsets; (2) studies of SLE patients' data obtained after contact with original author; (3) studies clearly indicated the dose and time of use

of ld IL-2; (4) studies limited to humans; (5) only the latest study to be included if duplicated studies from same population or database were reported. The exclusion criteria were as follows: (1) studies of Treg proportion data could not be determined; (2) studies of pregnant women and children under 18 years of age; (3) small.

Eligibility criteria The inclusion criteria were (1) studies reporting outcome measures that included clinical indexes and lym.

Information sources PubMed, Embase, the Cochrane database, Scopus and the Web of science for relevant studies published up to 22th August 2023**.**

Main outcome(s) 1.SLEDAI 2.24hUP 3.serum albumin 4.C3 C4 5.lymphocyte subsets**.**

Quality assessment / Risk of bias analysis Two investigators selected and identiffed relevant articles independently, and a third reviewer resolved any disagreements. The 2011 guidelines of the Oxford Center for Evidence-Based Medicine (OCEBM) were used to valuated the evidence levels of the studies. The NewcastleOttawa Quality Assessment Scale (NOQAS), which can be used to assess the quality of non-randomized studies, conducted quality assessment. And The quality of randomized controlled trials is based on Cochrane review entries.

Strategy of data synthesis Our primary outcomes were clinical indexes before and after ld IL-2 intervention. The stratiffcation strategy we adopted for the subgroup analysis was mainly by trail type and dosage and duration of the medication.

Subgroup analysis 1.SLEDAI 2.24hUP 3.serum albumin 4.C3 C4 5.lymphocyte subsets.

Sensitivity analysis For continuous outcomes (the proportions of Tregs among CD4+ T cells of patients), we calculated standardized mean differences (SMDs) and compared these values using a random effects model (REM) (the DerSimonian and Laird method) [14]. When Treg percentages were reported as medians with interquartile ranges (IQRs), according to Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (http://www. cochrane-handbook.org.), we calculated means and SD (SD = IQR/1.35). Heterogeneity among studies was investigated by Cochrane chi-square test. Egger's regression asymmetry test (P ≥ 0 05). was applied to assess potential publication bias. Preplanned sensitivity analysis was performed by omitting each study individually and calculating the remaining pooled effect. STATA 16.0 (Stata Corporation, College Station, Texas, USA) was used for statistical analyses.

Country(ies) involved China.

Keywords low dose IL-2;systemic lupus erythematosus; rheumatic diseases.

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