INPLASY PROTOCOL

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Corresponding author:
Zhitao Ying

yingzhitao001@163.com

Author Affiliation:
Department of Lymphoma, Peking University Cancer Hospital & Institute.

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Conflicts of interest:
None declared.

Efficacy and safety of anti-CD19 chimeric antigen receptor-T cells immunotherapy in patients with relapsed or refractory large B-cell lymphoma: a systematic review and meta-analysis

Zhu, J[1]; Song, Y[2]; Ying, Z[3].

Review question / Objective: **We aimed to conduct a meta-analysis to evaluate the efficacy and safety of anti-CD19 chimeric antigen receptor-T cells immunotherapy in patients with relapsed or refractory large B-cell lymphomas.**
Condition being studied: **Large B-cell lymphoma, as the most common non-Hodgkin lymphoma (NHL), acoounts for 30% of NHL with the rising incidence. The first line chemotherapy regimen could alleviate symptoms in 60%-70% LBCL patients, while 30%-40% of LBCL patients would be difficult to treat to relapse post the first response, with poor prognosis. Chimeric antigen receptor T cells(CAR-T) is the latest developed cell-immunotherapy in recent years and demonstrates remarkable achievements in lymphoblastic leukemia with its unique advantages.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 September 2021 and was last updated on 15 September 2021 (registration number INPLASY202190045).

INTRODUCTION

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METHODS

Search strategy: We started systematic search from databases: PubMed, Embase and Cochrane library from available papers in literature from inception to Aug. 2021 for potentially eligible studies.

Participant or population: Patients with advanced, relapsed, or chemotherapy-refractory large B cell lymphoma were included.

Intervention: (Chimeric Antigen Receptor T Cells) OR (CAR-T[Title/Abstract]) AND CD19[Title/Abstract].

Comparator: Not applicable.

Study designs to be included: Clinical trials and observational studies in full-text or conference abstract, case report is excluded.

Eligibility criteria: 1) Patients with advanced, relapsed, or chemotherapy-refractory large B cell lymphoma were included; 2) Cases were more than ten; 3) CD 19- CAR T cells immunotherapy; 4) Full-text in English.

Information sources: Databases: PubMed, Embase and Cochrane library from available papers in literature.

Main outcome(s): Efficacy outcome: objective response rate (ORR), progression free survival (PFS), overall survival (OS), complete response (CR), partial response (PR), cell amplification, cytokines. Safety outcome: Cytokine release syndrome (CRS), neurological event, decreased immunoglobulin.

Quality assessment / Risk of bias analysis: MINORS for non-randomized clinical trials, NOS criteria for case-control and cohort studies. MINORS, for single arm studies.

Strategy of data synthesis: Efficacy and Safety: The pooled odds ratios (event rate) estimate of ORR, CR, PR and safety outcomes with 95% confidence intervals (CI) were obtained using the random-effects model.

Subgroup analysis: 1) Commercial product / CAR-T from Laboratory. 2) Different combination therapy. Other analysis. CRS: cumulative meta-analysis by time (start date of trials).

Sensitivity analysis: We would find the source of heterogeneity through sensitivity analysis by eliminating literature one by one. The sensitivity analysis of the primary outcome will be provided.

Language: English.

Country(ies) involved: China.

Keywords: Large B-cell lymphoma, Chimeric antigen receptor T cells, immunotherapy, CAR-T cell therapy, meta-analysis.

Contributions of each author:

Author 1 - Jun Zhu.
Email: zhujun@csco.org.cn
Author 2 - Yuqin Song.
Email: songyuqin622@163.com
Author 3 - Zhitao Ying.
Email: yingzhitao001@163.com