INPLASY PROTOCOL

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Conflicts of interest:
There is no conflict of interest to be disclosed in this article.

Efficacy and Safety of Tripterygium Wilfordii Polyglycosides Tables in the Treatment of IgA Nephropathy: A protocol for systematic review and meta-analysis

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Review question / Objective: **This study aimed to systematically evaluate the efficacy and safety of TGt for the treatment of IgAN and to provide a reasonable basis for clinical practice.Therefore, all randomized controlled trials (RCT) of TGt alone or in combination with ACEI/ARB, hormones and immunosuppressants in the treatment of IgAN were searched in this study to systematically evaluate their effectiveness and safety, as well as to provide an evidence-based basis for rational clinical application of TGt for treating IgAN.**
Information sources: **We will search for articles from several electronic databases, including the Cochrane Library, Embase, PubMed, and Web of Science, in English. Chinese databases include CNKI, WanFang, VIP, and CBM. Keywords of the search mainly included: "Tripterygium Wilfordii Polyglycosides Tables","Tripterygium","IgA Nephropathy", "Glomerulonephritis, IgA","Randomized controlled trial","randomized","placebo".**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 January 2022 and was last updated on 30 March 2022 (registration number INPLASY202210037).

INTRODUCTION

Review question / Objective: **This study aimed to systematically evaluate the efficacy and safety of TGt for the treatment of IgAN and to provide a reasonable basis for clinical practice.Therefore, all randomized controlled trials (RCT) of TGt alone or in combination with ACEI/ARB, hormones and immunosuppressants in the treatment of IgAN were searched in this study to systematically evaluate their effectiveness and safety, as well as to provide an evidence-based basis for**

rational clinical application of TGt for treating IgAN.

Condition being studied: Efficacy and Safety of Tripterygium Wilfordii Polyglycosides Tables in the Treatment of IgA Nephropathy: A protocol for systematic review and meta-analysis. Data have been extracted and analyzed under the guidance of professionals; The team members are all doctors and masters; Team members have visiting experience in the United States.

METHODS

Search strategy: Eight Chinese and English databases (CNKI, WanFang, VIP, CBM, Cochrane Library, Embase, PubMed, and Web of Science) were searched for all clinical randomized controlled trials on TGt for IgAN treatment. The retrieval period ranged from database construction to December 15, 2021. In accordance with the clinical research strategy recommended by the Cochrane Handbook and PRINCIPLE of PICOS, it was determined that the retrieval mode mainly adopted a combination of subject words and free words. The subject words of the following keywords and their free words would be combined, including "Tripterygium Wilfordii Polyglycosides Tables","Tripterygium","IgA Nephropathy", "Glomerulonephritis, IgA","Randomized controlled trial", "randomized", "placebo". Table1 lists the search strategy used in Pubmed and other databases are searched in the same way.

Participant or population: The subjects were patients with IgAN diagnosed after renal biopsy, and no restrictions were imposed on age, sex, race, nationality, etc.

Intervention: The experimental group was treated with TGt alone and/or in combination with other drugs. Routine basic treatment was also given.

Comparator: The control group was given basic treatment as well as other drugs. For example, ACEI/ARB, hormones and immunosuppressants.

Study designs to be included: Randomized controlled trial (RCT).

Eligibility criteria: The population-intervention-comparators-outcomes-study design framework (PICOS) was adopted to guide the eligibility criteria.This systematic review and meta-analysis protocol followed the guidelines, of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P).

Information sources: We will search for articles from several electronic databases, including the Cochrane Library, Embase, PubMed, and Web of Science, in English. Chinese databases include CNKI, WanFang, VIP, and CBM. Keywords of the search mainly included: "Tripterygium Wilfordii Polyglycosides Tables", "Tripterygium","IgA Nephropathy", "Glomerulonephritis, IgA","Randomized controlled trial","randomized","placebo".

Main outcome(s): Complete remission rate; Effective remission rate.

Additional outcome(s): 24-Hour urine protein; Albumin; Serum creatinine; Incidence of adverse reactions.

Data management: EndnoteX9 literature management software.

Quality assessment / Risk of bias analysis: Using the Cochrane Risk assessment tool for bias recommended in the Handbook of Cochrane Systematic Review, the methodological quality of all included randomized controlled studies was evaluated by two investigators separately, with a third participant participating in the discussion when the results were inconsistent. The quality evaluation was mainly carried out from the following six aspects: random allocation method, allocation scheme concealment, blind method, selective reporting of research results, and other sources of bias.

Strategy of data synthesis: RevMan 5.3 software was employed for statistical analysis of data. First, odds ratios (OR) and 95% conficence intervals (CI) were adopted

to represent dichotomous variables, and the mean difference (MD) and 95%CI were obtained for continuous variables. Second, the X2 test was used to conduct the heterogeneity analysis of the results of the included studies, and the test standard was α=0.1. If P≥0.10 and I2≤50%. No statistical significance was found in the heterogeneity among the results, and a fixed-effects model was adopted for the combined analysis. If P < 0.10 and/or I2 > 50%, statistical methods (e.g., subgroup analysis) should be adopted to further analyze the source of heterogeneity. If no significant source of heterogeneity was found, the random-effects model was employed for pooled analysis. Third, RevMan software(version 5.3) was adopted for the sensitivity analysis and mapping. Each study was excluded separately, the effect size of the recombination was observed, and the results were compared with the initial results to explore the effect of a single study on the overall effect size of the combination and the robustness of the results. Lastly, Begger's funnel plot and Egger's linear regression test were used to detect the risk of publication bias.

Subgroup analysis: Literature with high heterogeneity may have a great impact on the overall results of the study, therefore, it is necessary to conduct heterogeneity tests on the results of the included literature. However, potential heterogeneity was inevitable. To reduce the impact on the results, it is necessary to explore factors that may lead to significant heterogeneity. For example, age, sex, intervention measures, control measures, sample size and treatment process of the patients were included in the study.

Sensitivity analysis: According to the results of the bias risk assessment and literature quality assessment, low-quality literature studies were deleted to confirm the stability of the results and improve the reliability of the results.

Language: English and Chinese.

Keywords: Tripterygium Wilfordii Polyglycosides Tables, IgA nephropathy, meta-analysis, systematic review, Protocol.

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Other relevant information: The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.