INPLASY PROTOCOL

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The authors declare that they have no conflicts of interest in this study.

The effect of Tripterygium extracts for patients with Henoch-Schonlein purpura nephritis: a systematic review and meta-analysis

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Review question / Objective: **The objective of this study is to systematically evaluate the effect of Tripterygium extracts for patients with Henoch-Schonlein purpura nephritis in reducing proteinuria and hematuria, protecting renal function, compared with placebo, usual standard treatment which is not include of any kind of Tripterygium extracts, or Chinese herbs which is not include of Tripterygium.**
Condition being studied: **Tripterygium extracts have been widely used in treatment of kidney and rheumatoid disease for many years in clinic. Clinical observation found Tripterygium extracts can reduce proteinuria and hematuria in kidney diseases include HSPN. The mechanism of effectiveness may be to inhibit immunity and reduce inflammation et.al, which is observed in vivo and vitro experiments. There is no meta-analysis about the effect of Tripterygium extracts for HSPN, but the exact efficacy of Tripterygium extracts for HSPN is unknown and the amount of controlled parallel intervention trails is available for a systematic review and meta-analysis.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 September 2020 and was last updated on 04 September 2020 (registration number INPLASY202090016).

INTRODUCTION

Review question / Objective: **The objective of this study is to systematically evaluate the effect of Tripterygium extracts for patients with Henoch-Schonlein purpura nephritis in reducing proteinuria and hematuria, protecting renal function, compared with placebo, usual standard treatment which is not include of any kind of Tripterygium extracts, or Chinese herbs which is not include of Tripterygium.**

Rationale: **HSPN is a kind of kidney damage by Henoch-Schonlein purpura, which main clinical manifestations include proteinuria, hematuria,and renal insufficiency. Long-term and severe**

proteinuria may aggravate the damage in renal function in HSPN. The current drug treatment has ACEI/ARB, glucocorticoid and immunosuppressants. ACEI/ARB cannot be used in CKD 3-5 stage and have adverse reactions. Glucocorticoid and immunosuppressants have many and severe adverse reactions, especially for children with HSPN.

Condition being studied: Tripterygium extracts have been widely used in treatment of kidney and rheumatoid disease for many years in clinic. Clinical observation found Tripterygium extracts can reduce proteinuria and hematuria in kidney diseases include HSPN. The mechanism of effectiveness may be to inhibit immunity and reduce inflammation et.al, which is observed in vivo and vitro experiments. There is no meta-analysis about the effect of Tripterygium extracts for HSPN, but the exact efficacy of Tripterygium extracts for HSPN is unknown and the amount of controlled parallel intervention trails is available for a systematic review and meta-analysis.

METHODS

Search strategy: The systematic search was conducted using the following database: Pubmed, Cochrane library, EMBASE, web of Science, CNKI, wanfang data, cqvip, CBM, Chinese clinical trial registry and US National Institutes of Health Ongoing Trials Register. The search consisted of MeSH terms and keywords related to HSPN and Tripterygium. ("purpura, schoenlein-henoch"[MeSH Terms] OR ((((((((((((("HSPN"[Title/Abstract] OR "henoch schoenlein purpura"[Title/Abstract]) OR "henoch Schonlein purpura"[Title/Abstract]) OR "allergic purpura"[Title/Abstract]) OR "anaphylactoid purpura"[Title/Abstract]) OR "Henoch purpura"[Title/Abstract]) OR "nonthrombocytopenic purpura"[Title/Abstract]) OR "non thrombocytopenic purpura"[Title/Abstract]) OR "peliosis rheumatica"[Title/Abstract]) OR "purpura rheumatica"[Title/Abstract]) OR "rheumatoid purpura"[Title/Abstract]) OR "Schonlein disease"[Title/Abstract]) OR "Schonlein disease"[Title/Abstract]) OR "purpura nephr*"[Title/Abstract])) AND ("Tripterygium"[MeSH Terms] OR (("triptolide"[Title/Abstract] OR "tripdiolide"[Title/Abstract]) OR "tripterine"[Title/Abstract])).

Participant or population: Patients with Henoch-Schonlein purpura nephritis at any age.

Intervention: Tripterygium extracts, e.g., Tripterygium glycosides, triptolide, tripterine, tripdiolide. Or Tripterygium extracts and usual standard treatment. There is no limit to the dosage of Tripterygium extracts and usual standard treatment.

Comparator: Placebo, usual standard treatment which is not include of any kind of Tripterygium extracts, or Chinese herbs which is not include of Tripterygium.

Study designs to be included: All RCTs and quasi-RCTs.

Eligibility criteria: Eligibility criteria needs (1) Participant must be Patients with Henoch-Schonlein purpura nephritis; (2)Intervention must be Tripterygium extracts or usual standard treatment with Tripterygium extracts; (3)Included study must be RCTs and quasi-RCTs; (4)The outcomes are based on proteinuria, hematuria and renal function.

Information sources: The systematic search was conducted using the following database: Pubmed, Cochrane library, EMBASE, web of Science, CNKI, wanfang data, cqvip, CBM, Chinese clinical trial registry and US National Institutes of Health Ongoing Trials Register. Article language was restricted in Chinese and English.

Main outcome(s): The main outcomes are the change in level of proteinuria and renal function from the baseline to the end of the intervention.

Additional outcome(s): Additional outcomes include the change in level of

hematuria from the baseline to the end of the intervention, the change in level of proteinuria and renal function obtained at any time during or after intervention, the change in liver function and blood routine examination, Total clinical response rate.

Data management: The data was managed and carried out by Endnote X8 and RevMan 5.3.

Quality assessment / Risk of bias analysis: The risk of bias of each included RCT or qusi-RCT will be evaluated by Cochrane ROB. Methodological quality (randomisation method, allocation concealment, blinding of participants, investigators, outcome assessors and data analysers, intention-to-treat analysis, and completeness of follow-up) of included studies will be assessed by the same reviewers, without blinding to author or source. Any discrepancies in methodological quality assessment or in data extraction will be resolved by discussion.

Strategy of data synthesis: Review Manager 5.3 software will be used for this statistical analysis. Risk ratio(RR) will be used for dichotomous outcomes and mean difference (MD) will be adopted for continuous outcomes. Statistical heterogeneity will be tested by examining I^2, with an I^2 greater than 50% indicating a possibility of statistical heterogeneity. A random effects model will be used for the meta-analysis if there is significant heterogeneity, and a fixed effect model will be used when the heterogeneity is not significant. The confidence interval (CI) will be established at 95%. Publication bias will be explored by funnel plot analyses.

Subgroup analysis: Subgroup analyses will be conducted if data is sufficient. We plan to divide participant into adult subgroup and child subgroup, divide participant by level of proteinuria, divide intervention into Tripterygium extracts subgroup and usual standard treatment with Tripterygium extracts to analysis.

Sensibility analysis: We will conduct sensitivity analyses to search for the potential sources of heterogeneity and reliability.

Language: The searching language limits in Chinese and English.

Country(ies) involved: China.

Keywords: HSPN, Tripterygium extracts, triptolide, Tripterygium glycosides, Meta-analysis.

Contributions of each author:
Author 1 - Yifan Shen - Develop the search strategy and draft the manuscript.
Author 2 - QI Jia - Work on study selection, quality assessment and data extraction.
Author 3 - Lin Han - Work on study selection, quality assessment and data extraction.
Author 4 - Gaimei Hao - Work on data synthesis.
Author 5 - Jianguo Qin - Assess the full-text with inclusion criteria.
Author 6 - Mingzhen Qin - Resolve divergences.