INPLASY PROTOCOL

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Review Stage at time of this submission: Formal screening of search results against eligibility criteria.

Conflicts of interest: None declared.

Efficacy of acupuncture combined with Chinese herbal medicine for the treatment of chronic nephritis: A protocol for systematic review and meta-analysis

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Review question / Objective: In order to better evaluate the efficacy of acupuncture combined with Chinese herbal medicine in the treatment of chronic nephritis, we conducted a systematic review and meta-analysis of published randomized clinical trials (RCTs) of such combined therapy in the treatment of chronic nephritis, hoping to provide evidence-based medical evidence and scientific reference protocols for the treatment of chronicnephritis.

Information sources: We will search eight electronic databases, including Web of Science, PubMed, Cochrane Library, Embase, China Biomedical Literature Database (CBM), China National Knowledge Infrastructure (CNKI), China Scientific Journal Database (VIP), and Wanfang database (Wanfang), from date of their inception to October 10, 2021. Keywords "acupuncture" ,"Chinese herbal medicine" and "chronic nephritis" will be used to retrieve the final set of chronic nephritis-related RCTs.

INTRODUCTION

Review question / Objective: In order to better evaluate the efficacy of acupuncture combined with Chinese herbal medicine in the treatment of chronic nephritis, we conducted a systematic review and meta-analysis of published randomized clinical trials (RCTs) of such combined therapy in the treatment of chronic nephritis, hoping to provide evidence-based medical

evidence and scientific reference protocols for the treatment of chronicnephritis.

Condition being studied: Chronic nephritis, a kidney disease that most commonly manifests as chronic glomerulonephritis, is currently viewed as a global public health problem that is increasingly attracting attention from the medical community . Chronic nephritis severity varies greatly, but the disease mainly manifests as hematuria, proteinuria and hypertension or edema that eventually worsen and lead to irreversible decline of kidney function. According to statistical data, the prevalence of chronic nephritis worldwide is approximately 8%-16% . The course of the disease is generally protracted and gradually progressive, although some patients experience acute exacerbations. At present, clinical treatment of this disease is challenging and prognosis is relatively poor, such that patients with chronic nephritis ultimately experience life-threatening renal failure. Current chronic nephritis treatments mainly include hormones, immunosuppressants, and symptomatic supportive therapies . However, long-term administration of these treatments can lead to adverse reactions, such as infection, digestive ulcers, obesity, osteoporosis, increased blood pressure, and elevated blood sugar. Based on various clinically recognized chronic nephritis symptoms, traditional Chinese Medicine (TCM) syndromes associated with the disease belong to categories of "edema" and "kidney wind" . Importantly, TCM treatment of chronic nephritis patients can significantly alleviate clinical symptoms, improve quality of life, and promote healthier levels of 24-h urinary total protein, hematuria, urinary microalbuminuria and other indicators. Meanwhile, acupuncture, a green TCM therapy often used in combination with other types of TCM interventions, offers advantages of treatment effectiveness for a broad range of indications, concurrent alleviation of symptoms and root causes, a clear curative effect, simple and economical operation, safety, and few side effects . Notably, acupuncture combined with Chinese herbal medicine has been shown to significantly alleviate chronic nephritis , although no systematic review yet has been conducted to analyze existing clinical data to determine the safety and efficacy of acupuncture-herbal medicine combination therapy, prompting this study. Here we conducted a systematic review and meta-analysis of published randomized clinical trials (RCTs) of acupuncture-herbal medicine combination therapy to gather scientific evidence with regard to safety and efficacy of this therapy and obtain reference protocols to guide administration of this treatment in a clinical setting.

METHODS

Participant or population: Adult patients who have been diagnosed with chronic nephritis, without regard to region, race, sex, age, education, course of disease, or duration of treatment, will be included.

Intervention: All patients included in the study received routine treatment for chronic nephritis. However, patients in intervention groups additionally received acupuncture combined with Chinese herbal medicine.

Comparator: All patients included in the study received routine treatment for chronic nephritis.

Study designs to be included: Only randomized controlled trials (RCTs) with complete clinical data will be included and RCTs will not be restricted based on blinding, country or region or Chinese or English-language.

Eligibility criteria: Only randomized controlled trials (RCTs) with complete clinical data will be included and RCTs will not be restricted based on blinding, country or region or Chinese or English-language.

Information sources: We will search eight electronic databases, including Web of Science, PubMed, Cochrane Library, Embase, China Biomedical Literature Database (CBM), China National Knowledge Infrastructure (CNKI), China

Scientific Journal Database (VIP), and Wanfang database (Wanfang), from date of their inception to October 10, 2021. Keywords "acupuncture" ,"Chinese herbal medicine" and "chronic nephritis" will be used to retrieve the final set of chronic nephritis-related RCTs.

Main outcome(s): Primary outcomes. overall efficacy (or overall response rate). Secondary outcomes. (1) 24-h urinary total protein (UTP) (g/24 h). (2) Serum creatinine (SCr) (μmol/L). (3) Blood urea nitrogen (BUN) (mmol/L). (4) Urine α1-microglobulin (α1-MG) (mg/L). (5) Urinary microalbuminuria (mALB)(mg/L).

Quality assessment / Risk of bias analysis: Two authors will independently appraise the methodological quality of each trial in six dimensions: selection bias, performance bias, detection bias, attrition bias, reporting, and other biases. Any disagreements will be resolved through discussions between the two authors or consultation with a third researcher . Articles not made available with complete clinical data will be excluded after several attempts have been made to contact the authors of those studies.

Strategy of data synthesis: All statistical analyses will be performed using Review Manager (RevMan) Version 5.4. Dichotomous variables will be expressed as odds ratio (OR) values and continuous variables will be expressed as mean difference (MD) values. Estimated values with 95% confidence interval (CI) values will be included to indicate statistical significance. All variables will be considered statistically significant at P < 0.05 unless otherwise specified. The I2 statistic and P-value will be computed to quantify heterogeneity. A fixed-effect model will be employed when no statistical heterogeneity (I2 < 50% and P > 0.1) across studies is found; otherwise, a random-effect model will be used, with subgroup analyses conducted of sex, age, course of disease to explore potential sources of heterogeneity. Sensitivity analysis will be performed to check the robustness of conclusions and identify outliers that markedly deviated from other trials by removing one study at a time. Reasons for variability will be explained.

Subgroup analysis: Due to potential heterogeneity that may adversely impact results of this study, after all information included in this study is collected, we could perform subgroup analysis based on sex, age and treatment duration of all included subjects.

Sensitivity analysis: A sensitivity analysis will be performed to assess the robustness of the final set of results. If the results are found to be unstable, studies with a high risk of bias will be excluded.

Country(ies) involved: China.

Keywords: acupuncture, Chinese herbal medicine, chronic nephritis, protocol, systematic review.

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