

INPLASY PROTOCOL

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Effective rate of different intervention methods in the treatment of hyperlipidemia: a protocol for systematic review and network meta-analysis

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Participant or population: Patients with a clear diagnosis of hyperlipidemia. Refer to "Guiding Principles for Clinical Research of New Chinese Medicines" or "Guidelines for the Prevention and Treatment of Dyslipidemia in Adults in China" or "Internal Medicine" in the diagnostic criteria for hyperlipidemia.

Intervention: Trials that compare combined interventions with individual interventions or individual interventions (for example, acupoint embedding + lipid-lowering drugs (atorvastatin calcium) and acupuncture) will be considered.

Information sources: PubMed, EMBASE, web of science, the Cochrane Library and the Chinese Biomedical Literature Database will be searched from the beginning to September 12, 2021. At the same time, the reference list of published reviews and retrieved articles will be checked for additional experiments.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 November 2021 and was last updated on 07 November 2021 (registration number INPLASY2021110022).

Condition being studied: HLP is a disorder of fat metabolism, which can cause a series of sclerosing cardiovascular and cerebrovascular diseases such as atherosclerosis and coronary atherosclerotic heart disease. According to the 2016 "Guidelines for the Prevention and Treatment of Dyslipidemia in Adults in

INTRODUCTION

Review question / Objective: According to the formulation of the PICO principle, P is the patient and the population, I is the intervention/exposure, C is the comparison/control, O is the result, and S is the study design.

China", the prevalence of dyslipidemia in Chinese adults is as high as 40%.4%, which is a substantial increase from 2002. The proportion of Chinese children and adolescents with hypercholesterolemia is also significantly higher. Previously, relevant domestic and foreign guidelines recommend giving statins to reduce the level of low-density lipoprotein cholesterol (LDL-C) in order to prevent the occurrence of cardiovascular diseases. However, the adverse reactions of statins often occur, including statin-related muscle symptoms (SAMS), liver damage, diabetes, cognitive impairment, and the risk of hemorrhagic stroke, which lead to poor patient compliance. Traditional Chinese medicine intervention plays a unique advantage in the prevention and treatment of chronic diseases. Current studies have found that acupoint embedding, acupuncture and auricular acupoint therapy have a significant positive effect on reducing patients' hyperlipidemia. Due to the lack of inter-research or indirect comparisons, we do not know which intervention has the best effect. When there are no studies that directly compare all relevant treatment options, a network meta-analysis (NMA) can be performed by comparing the relative effects of the treatment effectiveness of this study. NMA is considered to be an extension of the traditional meta-analysis of multiple treatments in a given condition. As a branch of traditional meta-analysis, network meta-analysis integrates existing research and forms an evidence network that can indirectly compare treatment effects. Before us, the value of NMA for medical decision-making has been recognized and accepted by different medical technology evaluation and funding agencies around the world. Therefore, we will conduct NMA to more comprehensively evaluate the effects of different interventions on hyperlipidemia.

METHODS

Search strategy: The main search terms are hyperlipidemia, dyslipidemia, hypercholesterolemia, hypertriglyceridemia, mixed hyperlipidemia

and their synonyms. Search strategy of PubMed as follows: #1“acupuncture therapy[Title/Abstract]) OR "acupuncture,ear" [Title/Abstract]) OR electroacupuncture[Title/Abstract]) OR meridians[Title/Abstract]) OR "acupuncture points"[Title/Abstract]) OR "fire needle"[Title/Abstract]) OR"acupoint catgut embedding"[Title/Abstract]) OR "moxibustion"[Title/Abstract]) OR "scalp acupuncture points"[Title/Abstract]) OR "bleeding"[Title/Abstract]) OR "needle knife"[Title/Abstract] #2 “ear acupuncture” [Title/Abstract] OR “auricular therapy” [Title/Abstract] #3 #1 OR #2 #4“Hyperlipemia” [Title/Abstract] OR “Hyperlipemias” [Title/Abstract] OR “Hyperlipidemia” [Title/Abstract] OR “Lipidemia” [Title/Abstract] OR “Lipidemias” [Title/Abstract] OR“Lipemia” [Title/Abstract] #5 #3 AND #4 #6“Randomized controlled trial”[Title/Abstract] OR “RCT”[Title/Abstract] OR “random*[Title/Abstract] OR blind*[Title/Abstract] OR singleblind*[Title/Abstract] OR doubleblind*[Title/Abstract] OR trebleblind*[Title/Abstract] #7 #5 AND #6.

Participant or population: Patients with a clear diagnosis of hyperlipidemia. Refer to "Guiding Principles for Clinical Research of New Chinese Medicines" or "Guidelines for the Prevention and Treatment of Dyslipidemia in Adults in China" or "Internal Medicine" in the diagnostic criteria for hyperlipidemia.

Intervention: Trials that compare combined interventions with individual interventions or individual interventions (for example, acupoint embedding + lipid-lowering drugs (atorvastatin calcium) and acupuncture) will be considered.

Comparator: A trial that will consider the treatment of traditional Chinese medicine to compare with no treatment, standard care, or regular physical activity.

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

Eligibility criteria: According to the formulation of the PICO principle, P is the

patient and the population, I is the intervention/exposure, C is the comparison/control, O is the result, and S is the study design.

Information sources: PubMed, EMBASE, web of science, the Cochrane Library and the Chinese Biomedical Literature Database will be searched from the beginning to September 12, 2021. At the same time, the reference list of published reviews and retrieved articles will be checked for additional experiments.

Main outcome(s): Main outcome indicators: total effective rate, blood lipids (total cholesterol (TC), triacylglycerol (TG), high-density lipoprotein cholesterol (HDL-C), LDL-C, lipoprotein A (ApoA), lipoprotein B (ApoB)).

Additional outcome(s): Secondary outcome indicators: BMI, clinical efficacy of traditional Chinese medicine, and adverse reactions.

Quality assessment / Risk of bias analysis: Two reviewers will independently use Cochrane Manual 5.1.0 to assess the quality of the included literature. We will resolve any disagreements by discussing or involving a third commenter. The manual includes random sequence generation, allocation hiding, participant and personnel blinding, result evaluation blinding, incomplete result data, selective reports, and other sources of deviation. We rate methodological quality as low, high, or unclear risk of bias. The bias in the randomized controlled trial will evaluate seven items: random sequence generation method (selection bias), allocation hiding (selection bias), participant and personnel blinding (performance bias), result evaluation blinding (detection bias), incompleteness Data (detection deviation), selective reporting (detection deviation), and other biases. Each item will be classified as high, low or ambiguous risk of deviation.

Strategy of data synthesis: Network evidence maps will be drawn to visually represent comparisons between studies.

The size of the node indicates the number of participants, and the thickness of the edge indicates the number of comparisons. Stata14 and OpenBUGS software will be used for Bayesian network meta-analysis. Bayesian inference will use the Markov chain Monte Carlo method. The posterior probability will be inferred from the prior probability. When the Markov chain Monte Carlo reaches a stable state of convergence, assumptions will be estimated and inferred. Therefore, the level of analgesic effect of different measures will be represented by the curve area or bar graph under the cumulative ranking curve. The node division method is used to evaluate the inconsistency between direct comparison and indirect comparison. By comparing the deviation information standards of each model, it is possible to choose between consistent and inconsistent models and fixed and random effects models. To rank the various treatments for each result, we will use SUCRA and average ranking.

Subgroup analysis: If there is a high degree of heterogeneity in the included studies, we will conduct a subgroup analysis to explore differences in age, gender, race and intervention time course.

Sensitivity analysis: To ensure the robustness of the comprehensive results, sensitivity analysis will be conducted to assess the impact of studies with high risk of bias. We will compare the results to determine whether low-quality studies should be excluded.

Country(ies) involved: China.

Keywords: hyperlipidemia; Network meta-analysis.

Contributions of each author:

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