INPLASY PROTOCOL

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Support: **Have support.**

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Conflicts of interest:
None declared.

Effectiveness comparisons of Chinese patent medicine containing red yeast rice on hyperlipidemia: A network meta-analysis of randomized controlled trials

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Review question / Objective: **Hyperlipidemia is a common disease resulting from abnormal lipid metabolism, considered as one of the high-risk factors of inducing cardio-cerebrovascular disease. Chinese patent medicines for eliminating phlegm, promoting blood circulation and removing blood stasis are often used to treat hyperlipidemia with phlegm-stasis cementation syndrome, such as Xuezhikang Capsule, Zhibituo Capsule, Jiangzhitongmai Capsule, Xiaoyujiangzhi Capsule, Zhibitai Capsule, Zhibitai Capsule. To compare the clinical efficacy and safety of those different oral Chinese patent medicines in the treatment of dyslipidemia by network Meta-analysis.**
Condition being studied: **Chinese patent medicines for eliminating phlegm, promoting blood circulation and removing blood stasis are often used to treat hyperlipidemia with phlegm-stasis cementation syndrome, such as Xuezhikang Capsule, Zhibituo Capsule, Jiangzhitongmai Capsule, Xiaoyujiangzhi Capsule, Zhibitai Capsule, Zhibitai Capsule. However, there is no study of compare the difference in efficacy between those medicines in treating hyperlipidemia with phlegm-stasis cementation syndrome.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 March 2021 and was last updated on 06 May 2021 (registration number INPLASY202130017).

INTRODUCTION

Review question / Objective: **Hyperlipidemia is a common disease resulting from abnormal lipid metabolism, considered as one of the high-risk factors of inducing cardio-cerebrovascular disease. Chinese patent medicines for**

eliminating phlegm, promoting blood circulation and removing blood stasis are often used to treat hyperlipidemia with phlegm-stasis cementation syndrome, such as Xuezhikang Capsule, Zhibituo Capsule, Jiangzhitongmai Capsule, Xiaoyujiangzhi Capsule, Zhibitai Capsule, Zhibitai Capsule. To compare the clinical efficacy and safety of those different oral Chinese patent medicines in the treatment of dyslipidemia by network Meta-analysis.

Rationale: Hyperlipidemia refers to hypercholesterolemia, hypertriglyceridemia and mixedhyperlipidemia, and is a very common biochemical disorder serious effect on health. Hyperlipidemia is closely related to many diseases, such as cardiovascular diseases, Alzheimer 's disease and type 2 diabetes. Traditional Chinese medicine(TCM) is widely used for dyperlipidemia in China. the phlegm and blood stasis is the main pathogenesis of hypercholesterolemia based on TCM theory. There are many kinds of Chinese patent medicines for eliminating phlegm, promoting blood circulation and removing blood stasis, but the effect and safety of has not been systematically evaluated.

Condition being studied: Chinese patent medicines for eliminating phlegm, promoting blood circulation and removing blood stasis are often used to treat hyperlipidemia with phlegm-stasis cementation syndrome, such as Xuezhikang Capsule, Zhibituo Capsule, Jiangzhitongmai Capsule, Xiaoyujiangzhi Capsule, Zhibitai Capsule, Zhibitai Capsule. However, there is no study of compare the difference in efficacy between those medicines in treating hyperlipidemia with phlegm-stasis cementation syndrome.

METHODS

Search strategy: A literature search will be performed in three Chinese (China National Knowledge Infrastructure [CNKI], Wanfang and VIP database) and three English-language (PubMed, Embase and Cochrane Library) databases, from their inception to March 10, 2021.

Participant or population: Patients met the diagnostic criteria for hyperlipidemia.

Intervention: The experimental group was administered any of the following Chinese patent medicine containing red yeast rice, including Xuezhikang Capsule, Zhibituo Capsule and Zhibitai Capsule, and without western medicine.

Comparator: The control group was treated with Simvastatin (Zocor).

Study designs to be included: The randomized controlled trials will be contained.

Eligibility criteria: The randomized controlled trials (RCTs) were contained. Trials with participants that were diagnosed with hyperlipidemia according to recognized diagnostic criterion were included, without the limitations of age, sex or ethnicity. The experimental group was administered any of the following Chinese patent medicine containing red yeast rice, including Xuezhikang Capsule, Zhibituo Capsule and Zhibitai Capsule, and without western medicine. The control group was treated with Simvastatin (Zocor). The outcomes were serum lipid levels, including TC, TG, LDL-C or HDL-C. Trials in Chinese or English were included.

Information sources: A literature search will be performed in three Chinese (China National Knowledge Infrastructure [CNKI], Wanfang and VIP database) and three English-language (PubMed, Embase and Cochrane Library) databases, from their inception to March 10, 2021.

Main outcome(s): The main outcomes were serum lipid levels, including TC, TG, LDL-C and HDL-C.

Additional outcome(s): The secondary outcomes included clinical efficacy and adverse drug reactions (ADRs).

Data management: Data from included studies will be extracted following structured forms with the relevant

information (e.g.,author's name, publication year, study design, sample size, characteristics of the patients, type of intervention, treatment course, outcomes, adverse events).

Quality assessment / Risk of bias analysis: The risk of bias tool from the Cochrane Handbook will be used to assessed the risk of bias in the included studies.

Strategy of data synthesis: The statistical software (STATA13.1, Stata Corporation) will be used to pool the data to conduct the meta-analysis.

Subgroup analysis: Subgroup analysis will be performed to assess possible biasing factors of meta results following the factors of course of treatment.

Sensitivity analysis: Sensitivity analyses will be conducted at factors may be strongly influence the results. For instance, whether the results are different when excluding the low-quality articles.

Country(ies) involved: the systematic review is being carried out in China.

Keywords: complementary medicine; hyperlipidaemia; meta-analysis; randomized controlled trials.

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