

INPLASY PROTOCOL

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None declared.

Effectiveness of garlic and its extracts on dyslipidemia : A network meta-analysis

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Review question / Objective: How effective are garlic and its extracts in treating dyslipidemia, in combination with lipid-lowering medications, compared with conventional drugs.

Condition being studied: Traditional lipid-lowering drugs such as statins has shown well-recognized efficacy in improving the blood fat level for patients with dyslipidemia. However, a small portion of patients would suffer Mild to serious side effects, such as gastrointestinal reactions, headaches, and rhabdomyolysis. Garlic extract has been found to be an effective lipid-lowering alternative therapy. However, the sample size of individual studies in this field is often too small. The network meta-analysis is to compare the effectiveness of garlic and its extracts with Traditional lipid-lowering drugs on dyslipidemia.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 October 2021 and was last updated on 19 October 2021 (registration number INPLASY2021100071).

INTRODUCTION

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improving the blood fat level for patients with dyslipidemia. However, a small portion of patients would suffer Mild to serious side effects, such as gastrointestinal reactions, headaches, and rhabdomyolysis. Garlic extract has been found to be an effective lipid-lowering alternative therapy. However, the sample size of individual studies in this field is often too small. The network meta-analysis is to

compare the effectiveness of garlic and its extracts with Traditional lipid-lowering drugs on dyslipidemia.

METHODS

Search strategy: Electronic databases were searched to identify randomised controlled trials (RCTs) : PubMed, Web of Science, EMBASE, The Cochrane Library, SinoMed, Chinese National Knowledge Infrastructure (CNKI), Chinese VIP information (VIP), and WanFang database. Studies published between the date of its inception and 18th October 2021 will be sought. The following terms and their thesauruses will be used: "Dyslipoproteinemia", "Dyslipoproteinemia", "dyslipidemia", "Hyperlipemia", "Hyperlipemias", "hyperlipedemia", "hypercholesterolemia", "hypertriglyceridaemia", "hypertriglyceridemia", "Lipidemia", "Lipidemias", "Lipemia", "Lipemias", "garlic", "Randomized controlled trial", "clinical trial". Subject headings searching will be used to match the above terms. There will be no language restrictions for the articles searching.

Participant or population: Participants with all types of dyslipidemia will be included without limitation of age, gender and race.

Intervention: The intervention group was given Garlic or garlic extract on the basis of conventional lipid-lowering drugs. Conventional lipid-lowering drugs include statins, Fibrates, Nicotinic Acids, bile acid sequestrants, Cholesterol absorption inhibitor and fixed ratio compound formulations composed of the above drugs.

Comparator: Conventional therapies such as statins, Fibrates, Nicotinic Acids and bile acid sequestrants.

Study designs to be included: Randomized controlled trials (RCTs) will be included.

Eligibility criteria: 1) Participants with dyslipidemia will be included without limitation of age, gender and race.

Dyslipidemia is defined as total cholesterol(TC) \geq 5.2mmol/L or low density lipoprotein(LDL-C) \geq 3.4mmol/L or high density lipoprotein(HDL-C) $<$ 1.0mmol/L or triglycerides(TG) \geq 1.7mmol/L without lipid-lowering drugs; (2)Interventions: The experimental group was administered garlic or garlic extract in combination with conventional lipid-lowering drugs. (3) Comparison: the control group was treated with conventional lipid-lowering drugs; (4)Study design: randomized controlled trials will be included; (5) Outcomes: reporting at least one of these outcomes: total effective rate of lipid control, total cholesterol (TC), low density lipoprotein cholesterol (LDL-C), high density lipoprotein cholesterol (HDL-C), triglyceride (TG).

Information sources: PubMed, Web of Science, EMBASE, The Cochrane Library, SinoMed, Chinese National Knowledge Infrastructure (CNKI), Chinese VIP information (VIP), and WanFang database will be searched by computer from inception to October 20, 2021, regardless of language. Grey literature, Chinese Clinical Trial Registry, and Clinical Trials will also be searched as supplements.

Main outcome(s): The main outcomes will include: total effective rate of lipid control, total cholesterol (TC), triglycerides (TG), high density lipoprotein (HDL) and low density lipoprotein (LDL).

Additional outcome(s): Additional outcomes will include but not limited to: aspartate aminotransferase (AST), Alanine aminotransferase (ALT).

Data management: The study selection and data extraction will be conducted by two authors independently. Any disagreement will be resolved by discussion until consensus is reached or by consulting a third author. The extracted information may consist of authors and title of articles, year and study size, age and gender of the participants, details of methodological information, details of treatment regimen, details of the control interventions

(including lipid-lowering drugs), outcomes, and adverse effects.

Quality assessment / Risk of bias analysis:

The risk of bias in included articles will be assessed by two authors independently . The quality of included trials will be assessed by using Cochrane Risk of bias tool and random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and selective reporting will be assessed. Discrepancies will be resolved through discussion or referral to a third reviewer.

Strategy of data synthesis: A descriptive synthesis of the findings from the included researches, including participants characteristics and intervention details will be performed. We will compute effect size by weighted mean differences/ standard mean difference (for continuous outcomes) with 95% CI or odds ratio (OR) with 95% CI (for binary outcomes). Heterogeneity will be considered significant and a random effect model will be used when $P > 50\%$. Meta analysis was performed using RevMan5.3 provided by the Cochrane collaboration network. Subgroup analysis and sensitivity analyses will be conducted to explore the heterogeneity of researches. If meta analysis is not appropriate, we will only perform a descriptive analysis. Evidence of publication bias will be accessed. And (GRADE) evidence profile in the meta-analysis will also be performed.

Subgroup analysis: Subgroup analyses will be done for age, duration of the disease and interventions. Or other factors should be considered if necessary.

Sensitivity analysis: We will ensure the stability of the comprehensive results by eliminating the sensitivity analysis of individual studies one by one.

Language: English.

Country(ies) involved: China.

Other relevant information: Yes, a similar but different topic titled "Effect of garlic and garlic products on lipid level in patients with hypercholesterolemia: a systematic review and network meta-analysis" be registering. The study focused only on patients with high cholesterol, whereas ours included patients with all types of dyslipidemia who met the relevant diagnostic criteria.

Keywords: Dyslipidemia; garlic; network meta-analysis; randomized controlled trials.

Contributions of each author:

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