

INPLASY PROTOCOL

To cite: Hong et al. The effectiveness of acupoint catgut embedding in hyperlipidemia with obesity: protocol for a systematic review and meta-analysis. Inplasy protocol 202040036. doi: 10.37766/inplasy2020.4.0036

Received: 07 April 2020

Published: 07 April 2020

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Support: No. 2018-
YF05-00210-SN

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

Conflicts of interest: None.

The effectiveness of acupoint catgut embedding in hyperlipidemia with obesity: protocol for a systematic review and meta-analysis

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Review question / Objective: We will conduct this systematic review and meta-analysis to investigate the therapeutic effect and safety of acupoint catgut embedding in hyperlipidemia with obesity and provide more options for its clinical treatment.

Information sources: We will collect clinical studies by searching the following database: PubMed, Embase, Web of Science, CENTRAL, and 4 Chinese databases (involve CNKI, Wanfang, VIP, CBM). Together, to find additional potential studies, grey articles will be reviewed and reference lists of articles retrieved and related journals will be searched manually. Of course, we will also contact the original author if there is missing or insufficient information in the eligible article.

Main outcome (s): The primary outcomes are the lipid-lowering and weight-lowering effect (include reduction of serum TC, TG, LDL-C, HDL-C, as well as BMI, WB, WC from baseline to the end of studies).

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 April 2020 and was last updated on 07 April 2020 (registration number INPLASY202040036).

INTRODUCTION

Review question / Objective: We will conduct this systematic review and meta-analysis to investigate the therapeutic effect and safety of acupoint catgut embedding in hyperlipidemia with obesity

and provide more options for its clinical treatment.

Condition being studied: Hyperlipidemia is a metabolic disorder disease, which is manifested by a decrease in serum high-density lipoprotein (HDL) or an increase in

serum total cholesterol (TC), triglyceride (TG) and low-density lipoprotein (LDL). In recent years, due to changes in individuals' lifestyle and dietary structure, the number of patients with hyperlipidemia has soared all over the world. In China, the overall prevalence rate of hyperlipidemia is about 30.9% in military officers, while the overall pooled-prevalence of total dyslipidemia was estimated at 25.3% in children and adolescents. Additionally, the prevalence in Russia is up to 45%. Cardiovascular disease (CVD) is the leading cause of death. Hyperlipidemia, as one of the pathological bases of atherosclerosis, significantly increases the risk of cardiovascular and cerebrovascular diseases. Besides, it also poses a threat to acute pancreatitis. Hyperlipidemia is usually companies with a sequence of metabolic diseases, especially obesity. Hyperlipidemia participates in obesity's development. Similarly, obesity can induce lipide metabolism disorder. Besides, obesity is also regarded as an independent risk factor for cardiovascular disease. Therefore, Hyperlipidemia with obesity sufferers a higher risk for the development of CVD. Additionally, search indicates obesity and hypertriglyceridemia significantly increase the risk for peripheral neuropathy on early-stage diabetes, independent of glucose control.

METHODS

Search strategy: We will collect clinical studies by searching the following database: PubMed, Embase, Web of Science, CENTRAL, and 4 Chinese databases (involve CNKI, Wanfang, VIP, CBM) with a language restriction of English and Chinese until January 28, 2020. Together, to find additional potential studies, grey articles will be reviewed and reference lists of articles retrieved and related journals will be searched manually. The search terms included Hyperlipidemias, Hyperlipemia, Hyperlipemias, Hyperlipidemia, Lipidemia, Lipidemias, Lipemia, Lipemias, Dyslipidemias, Dyslipidemia, Dyslipoproteinemias,

Dyslipoproteinemia, as well as obesity, Acupoint catgut embedding, catgut implantation, catgut embedding.

Participant or population: Participants who were both defined as hyperlipidemia and obesity are eligible to be included. The exclusion criteria are as follows: individuals who had accepted weight loss or Lipid-lowering therapy Within 12 weeks before screening; women who were lactating or of childbearing potential.

Intervention: The intervention group will use acupoint catgut embedding therapy.

Comparator: The control group will adopt a placebo, or no treatment, drugs (modern medicine or traditional Chinese medicine(TCM)), diet and exercise therapy, TCM therapies, other active treatments.

Study designs to be included: The type of study is limited to randomized controlled trials (RCTs) carried out in humans. If the experiment shows that the phrase is random and the b.

Eligibility criteria: RCTs that conducted to investigate the effectiveness of acupoint catgut embedding in hyperlipidemia with obesity, and included the outcomes of lipid level and weight indicators, will meet the eligibility criteria.

Information sources: We will collect clinical studies by searching the following database: PubMed, Embase, Web of Science, CENTRAL, and 4 Chinese databases (involve CNKI, Wanfang, VIP, CBM). Together, to find additional potential studies, grey articles will be reviewed and reference lists of articles retrieved and related journals will be searched manually. Of course, we will also contact the original author if there is missing or insufficient information in the eligible article.

Main outcome(s): The primary outcomes are the lipid-lowing and wight-lowing effect (include reduction of serum TC, TG, LDL-C, HDL-C, as well as BMI, WB, WC from baseline to the end of studies).

Additional outcome(s): The number of adverse events during this period.

Data management: Date management will be done using Endnote X8.

Quality assessment / Risk of bias analysis: The Cochrane collaborations' tool for accessing the risk of bias installed in RevMan V.5.3 will be used to investigate the quality of all selected trials. This accessing tool contains seven bias items, and each item is divided into three risk levels according to criteria. With this tool, two reviewers will access the risk level of each item in turn and independently judge the risk of bias of each trial. Then, the overall quality of the included studies will be presented at a glance through an automatically generated risk of bias graph or summary. Additionally, all disagreements will be settled with a discussion.

Strategy of data synthesis: We choose the RevMan V.5.3 to perform the statistical analysis of data. By convention, for continuous variables, we adopt the mean difference (MD) with 95% CIs to calculate the effect size. In addition, related risks (RRs) with 95% CIs will be applicable when it comes to dichotomous data. The heterogeneity can be implied through inspecting the forest plots and calculating I^2 statistics. If $P > .05$ or $I^2 < 50\%$, the studies are homogeneous, and the fixed-effect model can be selected. Otherwise, it is interpreted as significant heterogeneity, and we'll choose the random-effect model to execute data analysis. Furthermore, if significant heterogeneity is found in the meta-analysis, sensitivity analysis or subgroup analysis will be implemented as remedy to explore the sources of heterogeneity.

Subgroup analysis: We will establish subgroup according to the different comparisons, or other factors that may affect outcomes, such as age, interval and duration of treatment, diagnostic criteria, or quality of studies, etc.

Sensibility analysis: Sensitivity analysis will be performed to evaluate the quality and stability of meta-analysis results. One analysis solution is to incorporate with random-effect model. On the other hand, we can exclude each included study one by one and re-analysis these dates to pinpoint the trial that induced distinction and finally eliminate it from eligible studies.

Language: The language is limited to English and Chinese.

Countries involved: China.

Keywords: acupoint catgut embedding, hyperlipidemia, obesity, protocol, meta-analysis, systematic review.

Contributions of each author:

Author 1 - The author wrote the original draft and contributed to conceptualization, methodology and software.

Author 2 - The author provided help to the writing of original draft, conceptualization and methodology.

Author 3 - The author is responsible for data curation and investigation.

Author 4 - The author is responsible for data curation and investigation.

Author 5 - The author is responsible for supervision and writing of the review.