INPLASY PROTOCOL

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None declared.

Association between cardiovascular disease and gut microbial: a protocol for systematic review and meta analysis

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Review question / Objective: **The objective of this study will be to assess the association of differences in intestinal flora composition between patients with cardiovascular disease and controls.**
Condition being studied: **Cardiovascular disease (CVD) has become a major threat to human life and health. Recent studies suggested that gut microbes may play an important role in maintaining cardiometabolic health and the pathophysiology of several diseases, including CVD.To address this knowledge lack, we will perform a systemic review and meta-analysis to evaluate the effect of cardiovascular disease on the Intestinal flora. We provide here a protocol that will outline the methods and analyses planned for the systematic review.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 December 2021 and was last updated on 19 January 2023 (registration number INPLASY2021120016).

INTRODUCTION

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including CVD.To address this knowledge lack, we will perform a systemic review and meta-analysis to evaluate the effect of cardiovascular disease on the Intestinal flora. We provide here a protocol that will outline the methods and analyses planned for the systematic review.

METHODS

Participant or population: Studies were included in our meta-analysis if they met the following criteria: 1) prospective or retrospective cohorts will be included in this study; 2) published in peer-reviewed journals; 3) reported CVD and intestinal flora. The exclusion criteria were as follows: 1) family-based studies; 2) case-only studies; 3) no information on CVD and intestinal flora; 4) editorials, narrative reviews or other manuscripts not reporting primary data. If the paper, or author correspondence, suggested overlapping studies, we included only the most comprehensive study for meta-analysis.

Intervention: Presence of CVD.

Comparator: No CVD.

Study designs to be included: Prospective or retrospective cohorts will be included in this study.

Eligibility criteria: Studies were included in our meta-analysis if they met the following criteria: 1) prospective or retrospective cohorts will be included in this study; 2) published in peer-reviewed journals; 3) reported CVD and intestinal flora. The exclusion criteria were as follows: 1) family-based studies; 2) case-only studies; 3) no information on CVD and intestinal flora; 4) editorials, narrative reviews or other manuscripts not reporting primary data. If the paper, or author correspondence, suggested overlapping studies, we included only the most comprehensive study for meta-analysis.

Information sources: A comprehensive literature search will be conducted in PubMed, Embase, Cochrane Library, SinoMed, China National Knowledge Infrastructure(CNKI), Wanfang Data and VIP Data, up to June 2021. The search will be based on predefined search terms by the Medical Subject Headings (MeSH), with combinations of 'coronary artery disease', 'cardiovascular disease', 'Angina Pectoris', 'Angina, Stable', 'Angina, Unstable', 'Angina Pectoris', 'Variant', 'Microvascular Angina', 'Intestinal flora'. Our search strategy includes the usage of Boolean operators, proximity operators, truncations and MeSH.

Main outcome(s): Differential abundance of intestinal flora in cardiovascular disease. Abundance values of intestinal flora in the disease and control groups in cardiovascular disease. Odds ratio for intestinal flora levels in the cardiovascular disease group to control group. Risk Ratio for different intestinal flora levels in cardiovascular disease.

Quality assessment / Risk of bias analysis: Newcastle-Ottawa scale (NOS) will be used for assessing studies' quality. This system uses three criteria:1) participant selection (maximum of four stars); 2) comparability of study groups (maximum of two stars) ;and 3) assessment of outcome or exposure (maximum of three stars) for the outcome/ exposure category.

Strategy of data synthesis: Review Manager 5.4 software and StataMP 16.0 will be used for data synthesis. Standardized mean difference will be used for estimate of the combined effect sizes. The heterogeneity assumption will be evaluated by I^2 statistics, ($I^2 > 50\%$, means large heterogeneity; $25\% < I^2 \leq 50\%$, means medium heterogeneity; and $0 \leq I^2 \leq 25\%$, means small heterogeneity). If there is no evidence showing large heterogeneity, a fixed effect model analysis will be used; otherwise, random effect model analysis will be chosen after excluding the sources of heterogeneity. 95% confidence intervals of all results will be calculated, the significance will be determined by Z-test, with a P value < 0.05 as a significant level. Newcastle-Ottawa-Scale(NOS) will be used for assessing risk of bias of individual studies.

Subgroup analysis: We will perform sensitivity analysis by the use of subgroup meta-analyses.

Sensitivity analysis: We will conduct a meta-regression analysis, using study gender proportions, age, age range, mean age±SEM, BMI, geographical differences in the CVD, etc.

Country(ies) involved: China, Japan.

Keywords: Cardiovascular disease, Intestinal flora, Meta-analysis.

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