INPLASY PROTOCOL

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Conflicts of interest:
The authors declare no conflicts of interest.

The effects of probiotics supplementation on renal function and oxidative stress in diabetic nephropathy: A systematic review and meta-analysis

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Review question / Objective: **The effects of probiotics supplementation on renal function and oxidative stress in diabetic nephropathy.**
Condition being studied: **The objective of this study is to evaluate the renal function and oxidative stress in diabetic nephropathy.**
Information sources: **The mainly searches Cochrane Library, Pubmed, EMBASE, and Web of Science. we will retrieve clinical trial registries and grey literature.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 July 2020 and was last updated on 11 July 2020 (registration number INPLASY202070037).

INTRODUCTION

Review question / Objective: **The effects of probiotics supplementation on renal function and oxidative stress in diabetic nephropathy.**

Condition being studied: **The objective of this study is to evaluate the renal function and oxidative stress in diabetic nephropathy.**

METHODS

Search strategy: **The study only selects clinical randomized controlled trials of probiotics supplementation for diabetic nephropathy. We will search each database**

from the built-in until August 2020. The mainly searches Cochrane Library, Pubmed, EMBASE, and Web of Science. we will retrieve clinical trial registries and grey literature.We will use MeSH Term: probiotics, diabetes mellitus, diabetic nephropathy, diabeyic kidney disease, diabetic chronic renal disease. Meanwhile, we will retrieve clinical trial registries and grey literature. Language: English.

Participant or population: Patients with diabetic nephropathy that received probiotics or placebo.

Intervention: Probiotics supplementation or probiotics contained food.

Comparator: Relevant other supporitive treatment for diabetic nephropathy or placebo.

Study designs to be included: Patients with diabetic nephropathy that received probiotics.

Eligibility criteria: Patients with diabetic nephropathy that received probiotics.

Information sources: The mainly searches Cochrane Library, Pubmed, EMBASE, and Web of Science. we will retrieve clinical trial registries and grey literature.

Main outcome(s): The indexes of renal function: Urinary albumin, UACR, Scr, BUN, eGFR, ALB, Potassium , Sodium; and indexes of oxidative stress: NO, GSH, TAC, MDA, were evaluated as the main outcomes.

Additional outcome(s): While several secondary outcomes were also evaluated in this study: BMI, FBG, A1c, Insulin, HOMA-IR, CRP, TC, TG, HDL-C, LDL-C.

Data management: The statistical analysis of this meta-analysis was conducted by RevMan software version.

Quality assessment / Risk of bias analysis: Quality assessment of RCTs adopts the risk of bias (ROB) assessment tool provided by the Cochrane Handbook. The following 7 items, such as random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other bias, are evaluated by 3 grades of “low bias,” “high bias,” and “unclear bias.” The discrepancies will get a consistent conclusion by discussing between both reviewers or seeking the third-party consultation.

Strategy of data synthesis: Review Manager software version 5.3 provided by the Cochrane Collaboration will be performed for data synthesis and analysis. The dichotomous data is represented by RR, continuous data is expressed by MD or SMD. If there is no heterogeneity (I2.1), the data is synthesized using a fixed effect model. Otherwise (I2≥50%, P<.1), a random effect model is used to analyze. Then subgroup analysis will be conducted based on the different causes of heterogeneity. If a meta-analysis cannot be performed, it will be replaced by a general descriptive analysis.

Subgroup analysis: If the results of the study are heterogeneous, we will conduct a subgroup analysis for different reasons. Heterogeneity is manifested in the following several aspects, such as race, age, gender, different intervention forms, pharmaceutical dosage, treatment course.

Sensibility analysis: Sensitivity analysis is mainly used to evaluate the robustness of the primary outcome measures. The method is that removing the low-level quality study one by one and then merging the data to assess the impact of sample size, study quality, statistical method, and missing data on results of meta-analysis.

Language: In English only.

Country(ies) involved: China.

Keywords: Diabetic Nephropathy; probiotic; gut microbiota; oxidative stress; renal function.

Dissemination plans: This systematic review and meta-analysis will be published in a peer-reviewed journal.

Contributions of each author:
Author 1 - Han Wang - Conceptualization; Writing-original draft.
Author 2 - Qiong Liu - Formal analysis.
Author 3 - Hongxin Song - Methodology.
Author 4 - Weipeng Yang - Supervision.
Author 5 - Hainan Wang - Writing – review & editing.