

INPLASY PROTOCOL

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None declared.

Efficacy and safety of traditional Chinese medicine based on the method of "nourishing kidney and clearing heat" as adjuvant in the treatment of diabetes mellitus patients with periodontal disease: A protocol for systematic review and meta-analysis

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Review question / Objective: Meta Analysis of the effectiveness of Randomized controlled Trials of traditional Chinese Medicine based on the method of "nourishing kidney and clearing heat" as adjuvant in the treatment of diabetes mellitus patients with periodontal disease.

Information sources: The computer searches the databases of PubMed, Cochrane Library, EMBASE, Web of Science, China National Knowledge Infrastructure(CNKI), VIP Database, Chinese Biometical Database, Wangfang Database.

Main outcome(s): Probing pocket depth (PPD) and/or clinical attachment loss (CAL) and/or plaque index (PLI) and/or sulcular bleeding index (SBI).

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 October 2021 and was last updated on 03 March 2022 (registration number INPLASY2021100007).

INTRODUCTION

Review question / Objective: Meta Analysis of the effectiveness of Randomized controlled Trials of traditional Chinese Medicine based on the method of "nourishing kidney and clearing heat" as

adjuvant in the treatment of diabetes mellitus patients with periodontal disease.

Condition being studied: Diabetes mellitus is a metabolic disease characterized by hyperglycemia, and its complications are diverse and harmful. At present, more than

422 million people in the world suffer from diabetes mellitus, and the incidence in China is also increasing. Periodontitis is the main cause of tooth loss in adults. Epidemiological studies show that about two-thirds of the world's population suffers from periodontal disease. In recent years, researchers have paid more and more attention to the close relationship between periodontitis and diabetes and other systemic diseases. Some scholars have suggested that periodontitis is the sixth major complication of diabetes, and both are risk factors for each other. Traditional Chinese medicine thinks that diabetes mellitus patients with periodontal disease is mostly related to the deficiency of "kidney yin", and the method of "nourishing kidney and clearing heat" combined with conventional western medicine treatment has been proved to be effective and has obvious advantages after long-term clinical application and relevant clinical research. Therefore, we will make a systematic evaluation and meta-analysis on the efficacy and safety of "nourishing kidney and clearing heat" as adjuvant in the treatment of diabetes mellitus patients with periodontal disease.

METHODS

Participant or population: The subjects of the study should meet the diagnostic criteria of western medicine, there are no restrictions on the sex, age, ethnic, background, occupation, course of disease.

Intervention: Experimental group: Traditional Chinese medicine prescription based on the method of "nourishing kidney and clearing heat", combined with conventional western medicine. We will not set limitations on dosages and course of treatment.

Comparator: Control group: western medicine routine treatment.

Study designs to be included: RCTs with or without blind methods, that report the application of "nourishing kidney and clearing heat" therapy for diabetes mellitus

patients with periodontal disease will be included.

Eligibility criteria: Reported in Chinese and English, and meet the "PICOS" will be taken into account, Details are as follows: 1. The subjects of the study should meet the diagnostic criteria of western medicine, and the sex, age, ethnic, background, occupation, course of disease of the diabetes mellitus patient with periodontal disease unlimited; 2. The experimental group was treated with prescription based on the theory of "nourishing kidney and clearing heat", with western medicine routine treatment; 3. The control group was treated with routine western medicine alone; 4. The outcomes included main outcomes (probing pocket depth (PPD) and/or clinical attachment loss (CAL) and/or plaque index (PLI) and/or sulcular bleeding index (SBI)) and/or secondary outcomes (tooth mobility (TM) and/or glycosylated hemoglobin A1c (HbA1c) and/or fasting blood-glucose (FPG) and/or c reactive protein (CRP) and/or gingival crevicular fluid IL-16 and/or gingival crevicular fluid p.g and/or bleeding on probing (BOP) total effective rate and/or adverse effects). 5. The type of study is randomized controlled trial, clinical study, whether using blind method or not.

Information sources: The computer searches the databases of PubMed, Cochrane Library, EMBASE, Web of Science, China National Knowledge Infrastructure (CNKI), VIP Database, Chinese Biometical Database, Wangfang Database.

Main outcome(s): Probing pocket depth (PPD) and/or clinical attachment loss (CAL) and/or plaque index (PLI) and/or sulcular bleeding index (SBI).

Additional outcome(s): Tooth mobility (TM) and/or glycosylated hemoglobin A1c (HbA1c) and/or fasting blood-glucose (FPG) and/or c reactive protein (CRP) and/or bleeding on probing (BOP) and/or gingival crevicular fluid IL-16 and/or gingival crevicular fluid p.g total effective rate and/or adverse effects.

Quality assessment / Risk of bias analysis:

Two authors will independently assess the risk of bias, The bias risk assessment tool of Cochrane system evaluator manual 5.4 was used to assess the bias risk of the included RCT, which including 7 items: random sequence generation, allocation concealment, blinding method, incomplete outcome data, selective reporting, and other biases. The quality of each trial will be divided into 3 levels: low bias risk, high bias risk, and unclear bias risk. Two authors will exchange assessment results and check whether the assessment results are consistent. If there is a disagreement, the third author will participate in the discussion and determine the final result.

Strategy of data synthesis: Meta analysis will be performed using Rev Man 5.4.0 software. The odds ratio (OR) and its 95% Confidence Interval (CI) will be used as the counting data, while the weighted mean difference (WMD) and its 95% CI will be used as the measurement data. The I² test will be used to assess statistical heterogeneity. Results of the meta-analysis will be visualised by forest plots. Sensitivity and subgroup analyses will be performed to explore the potential origins of significant heterogeneity.

Subgroup analysis: The heterogeneity test will be carried out first among all studies, I² test will be used. When $P > 0.1$ and $I^2 < 50\%$, the fixed effect model will be used; otherwise, If there is statistical heterogeneity among the results ($p > 50\%$), the random effect model is used to estimate the combined effect, and a subgroup analysis will be conducted to explore the source of the heterogeneity, including different outcomes.

Sensitivity analysis: To ensure the stability and reliability of the results, a sensitivity analysis will be performed by excluding the low-quality or high-weight studies one by one, and the results will be compared and discussed.

Language: No restriction.

Country(ies) involved: China.

Keywords: diabetes mellitus patients with periodontal disease; nourishing kidney and clearing heat; meta-analysis; protocol.

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