INPLASY PROTOCOL

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None declared.

Efficacy and Safety of the Chinese Patent Bazhen Decoction on Type 2 Diabetes Mellitus Patients: A Systematic Review and Meta-Analysis

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Review question / Objective: **Bazhen Decoction (BZD) is a proprietary Chinese medicine for the treatment of diabetes mellitus and is widely used in China for the treatment of diabetes mellitus and its complications. However, the efficacy of BZD in type 2 diabetes mellitus (T2DM) has not been fully evaluated. The aim of this study is to systematically evaluate the efficacy and safety of BZD in the treatment of T2DM.The aim of this study is to systematically evaluate the efficacy and safety of Bazhen Decoction in the treatment of T2DM.**
Information sources: **Seven databases were searched by computer, including PubMed, Cochrane Library, Embase, Web of Science, China Knowledge Infrastructure (CNKI), China Biomedical CD-ROM (Sino Med), Wanfang database and Vipers database (VIP), with a search time frame from inception to May 2022. The main aim of the first search was to collect literature comprehensively. The search methods included similar keyword search, subject term search, arbitrary term search, subject and abstract search with the following search terms: "Bazhen Decoction", "Bazhen Soup", "Bazhen Tang", "Bazhen" "Diabetes Mellitus", " Type 2 Diabetes Mellitus", "Diabetes Insipidus," "Diet, Diabetic," " Prediabetic State," "Glycation End Products, Advanced," "Gastroparesis," and "Glucose Intolerance." etc.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 May 2022 and was last updated on 28 May 2022 (registration number INPLASY202250155).

INTRODUCTION

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BZD in type 2 diabetes mellitus (T2DM) has not been fully evaluated. The aim of this study is to systematically evaluate the efficacy and safety of BZD in the treatment of T2DM.The aim of this study is to systematically evaluate the efficacy and safety of Bazhen Decoction in the treatment of T2DM.

Condition being studied: Type 2 diabetes mellitus.

METHODS

Participant or population: We included only adult patients with a clear diagnosis of T2DM, regardless of gender, region and ethnicity. Patients with type 2 diabetes were included who met the diagnostic criteria for diabetes published by the WHO in 1999 [25], including symptoms of diabetes (typical symptoms include "three more and one less") plus one of the following three diagnostic criteria: random blood glucose (blood glucose at any time of the day) ≥ 11.1 mmol/L (200 mg/dL). Fasting blood glucose (FBG; fasting is defined as no calories consumed for at least 8 hours) ≥ 7.0 mmol/L (126 mg/dL); glucose ≥ 11.1 mmol/L (200 mg/dL) 2 hours after glucose load.

Intervention: Bazhen Decoction.

Comparator: The control group was treated with Western medicine.

Study designs to be included: RCTs.

Eligibility criteria: All included studies were published clinical randomised controlled trials (RCTs), whether blinded or not.

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Main outcome(s): The primary outcome indicators are fasting blood glucose (FBG), two-hour postprandial glucose (2hPG), glycosylated hemoglobin (HbA1c).

Additional outcome(s): The secondary outcome indicators are total cholesterol (TC), triglycerides (TG), and total effective rate. total cholesterol (TC), triglycerides (TG), and total effective rate (TER). Safety is measured by adverse effects.

Quality assessment / Risk of bias analysis: Based on the Cochrane method of systematic evaluation, we first screened each study by title and abstract and then performed a second screening based on the full text. Disagreements were resolved through discussion with a third researcher. The quality of the literature was assessed using the risk of bias assessment tool provided in RevMan 5.4, including the identification of random sequences of selectivity bias, hidden selection bias in allocation, performance bias between participants and personnel, assessment of test bias, completeness of outcome data, bias and selective reporting, and other associated biases. Each item assessed was categorised as 'High risk' 'Low risk' and 'Unclear risk'.

Strategy of data synthesis: Meta-analysis was performed using Rev Man 5.4 software. In this study, the dichotomous variables were expressed as risk ratio (RR) and the continuous variables were expressed as mean differences (MD), and all effect sizes were expressed with 95% confidence intervals (CI). The I2 test was used to determine the heterogeneity of the results of the included studies. The heterogeneity test: when P 50%, the heterogeneity is high and the random-

effects model is used, while when P>0.10 and I2 ≤ 50%, the heterogeneity is low and the fixed-effects model is used.

Subgroup analysis: Subgroup analyses were constructed to explore potential causes of heterogeneity. The subgroup analysis focused on the following factors: different ages (8 weeks).

Sensitivity analysis: Sensitivity analyses were performed by removing studies with a high risk of bias and recalculating pooled data to assess the robustness of the combined results when the results were unstable.

Country(ies) involved: China.

Keywords: Chinese Patent; Bazhen Decoction; Type 2 Diabetes Mellitus; Meta-Analysis.

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