INPLASY PROTOCOL

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None.

Comparative efficacy and safety of traditional Chinese patent medicine for the treatment of type 2 diabetes mellitus: A Bayesian network meta-analysis protocol

Li, J[1]; Zhao, S[2]; Huang, Y[3]; Li, C[4]; Li, B[5]; Xu, Y[6].

Review question / Objective: **This study intends to explore the efficacy and safety of different TCPMs against T2DM through the network meta-analysis (NMA).**
Information sources: **We have systematically studied the skills and precautions of literature retrieval before literature retrieval, and worked out the final retrieval strategy after several pre searches. We will search the following sources regardless of date, language or publication status: PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Library, Web of Science, China National Knowledge Infrastructure(CNKI), Wanfang Database. We will apply a combination of medical subject headings (MeSH) and free text terms, combined with a database-specific search specification to implement a search strategy. The search start and end time is from the establishment of the database to August 2020. We will also search for ongoing trials registered on the World Health Organization's International Clinical Trials Registration Platform.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 August 2020 and was last updated on 30 August 2020 (registration number INPLASY202080125).

INTRODUCTION

Review question / Objective: **This study intends to explore the efficacy and safety of different TCPMs against T2DM through the network meta-analysis (NMA).**

Condition being studied: **Type 2 diabetes mellitus.**

METHODS

Participant or population: **Patients who have been diagnosed will follow the American Diabetes Guidelines. There are no restrictions on gender, age, course of disease, TCM syndrome, and race. Case**

number in the treatment group and the control group are both ≥30.

Intervention: The T2DM patients in the experimental group are treated with traditional Chinese patent medicines (TCPMs) combined with conventional therapy. The use of TCPM is limited to oral administration, regardless of the course and dose.

Comparator: T2DM patients in the control group are treated with conventional therapy.

Study designs to be included: RCTs.

Eligibility criteria: RCTs published in full Chinese or English language for the treatment of Type 2 diabetes mellitus with TCPMs, without restriction on the use of blind methods.

Information sources: We have systematically studied the skills and precautions of literature retrieval before literature retrieval, and worked out the final retrieval strategy after several pre searches. We will search the following sources regardless of date, language or publication status: PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Library, Web of Science, China National Knowledge Infrastructure(CNKI), Wanfang Database. We will apply a combination of medical subject headings (MeSH) and free text terms, combined with a database-specific search specification to implement a search strategy. The search start and end time is from the establishment of the database to August 2020. We will also search for ongoing trials registered on the World Health Organization's International Clinical Trials Registration Platform.

Main outcome(s): The primary outcomes are the fasting blood glucose (FBG), 2-hour postprandial blood glucose(2hPG), glycosylated hemoglobin A1c (HbA1c) and adverse events (including gastrointestinal symptoms, rash, hypoglycemia, etc).

Additional outcome(s): The secondary outcomes are as follows: (1) body Body mass index (BMI); (2) fasting Fasting insulin and 2-h postprandial insulin; (3) homeostasis Homeostasis model assessment-insulin resistance (HOMA-IR) ; (4) Homeostasis model assessment-β (HOMA-β).

Quality assessment / Risk of bias analysis: Two researchers will independently evaluate the methodological quality of the included studies, and resolve differences through discussion. The risk of bias will be assessed according to the Cochrane Handbook, which consisted of six items: Random sequence generation; Allocation hiding; Blinding of patients and trial personnel; Blinding of outcome evaluators; Incomplete result data; Selective reporting; Other biases (such as potential biases related to special research design, statement fraud, etc.). According to the relevant evaluation criteria, the included studies will be judged as "low risk of bias", "high risk of bias" and "uncertain risk of bias".

Strategy of data synthesis: We have systematically studied the skills and precautions of literature retrieval before literature retrieval, and worked out the final retrieval strategy after several pre searches. We will search the following sources regardless of date, language or publication status: PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Library, Web of Science, China National Knowledge Infrastructure(CNKI), Wanfang Database. We will apply a combination of medical subject headings (MeSH) and free text terms, combined with a database-specific search specification to implement a search strategy. The search start and end time is from the establishment of the database to August 2020. We will also search for ongoing trials registered on the World Health Organization's International Clinical Trials Registration Platform.

Subgroup analysis: If there is sufficient evidence, subgroup analysis will be conducted to explore the sources of

heterogeneity, including age, country, course of disease.

Sensibility analysis: Sensitivity analysis will be used by excluding each qualified study. After excluding a study, if the heterogeneity changes, then this study may be the source of the heterogeneity. We will further analyze and explain the reason why the document became the origin of the heterogeneity. If the heterogeneity remains the same after excluding individual documents, then indicates that our results of this study are relatively robust.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: Type 2 diabetes mellitus; traditional Chinese patent medicine; Bayesian; network meta-analysis; protocol.

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