INPLASY PROTOCOL

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Corresponding author:
Yan Yang

outsidersh@126.com

Author Affiliation:
Affiliated Hospital of Chengdu University of TCM

Support: **It's not clear yet.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None.

Effect of Shenqi compound on Inflammatory Markers and Glycemic Measures among Diabetes Mellitus : A Systematic Review of Randomized Controlled Trials

Yang, Y[1]; Zhong, W[2]; Tian, Y[3]; Zhou, H[4]; Xie, CG[5].

Review question / Objective: **Can Shenqi compound, established under the guidance of traditional Chinese medicine theory, control blood glucose and reduce inflammation markers of diabetes mellitus?**
Condition being studied: **Some randomized clinical trials RCT found that Shenqi compound can improve the inflammation markers of diabetes mellitus.**
Information sources: **PubMed, Embase, the Cochrane Library Central Register of Controlled Trials, and 4 Chinese databases including China National Knowledge Infrastructure (CNKI) database, Wanfang Data Knowledge Service Platform, the VIP information resource integration service platform (cqvip), China Biology Medicine Disc (Sino Med).**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 April 2020 and was last updated on 26 April 2020 (registration number INPLASY202040179).

INTRODUCTION

Review question / Objective: **Can Shenqi compound, established under the guidance of traditional Chinese medicine theory, control blood glucose and reduce inflammation markers of diabetes mellitus?**

Rationale: **Diabetes is a very common chronic disease, which seriously endangers human health.Shenqi compound prescription has been proved to be a very useful traditional Chinese medicine prescription for the treatment of diabetes and its related complications. The chronic inflammatory state of diabetes is probably the important physiological basis of its**

complications.Therefore we think it is necessary to systematically analyze the effect of Shenqi compound on inflammatory markers.

Condition being studied: Some randomized clinical trials RCT found that Shenqi compound can improve the inflammation markers of diabetes mellitus.

METHODS

Search strategy: Three English database including PubMed, Embase, Cochrane Library Central Register of Controlled Trials, and 4 Chinese databases including China National Knowledge Infrastructure (CNKI) database, Wanfang Data Knowledge Service Platform, the VIP information resource integration service platform (cqvip), China Biology Medicine Disc (Sino Med) will be searched from their inception to May 2020 with a language limitation of English and Chinese. In addition, Google scholar and Baidu Scholar will be used to find out potential missing papers. There is no time limitation about literatures. The Chinese Clinical Trial Registry (ChiCTR) and ClinicalTrials. gov will be searched to ensure that no clinical studies are missed. To obtain literature as comprehensively as possible, we will retrieve all the literature related to SC and then screen it according to inclusion and exclusion criteria. The search terms used will be as follows: "shenqi fufang," "shenqi compound," "SHEN-QI compound," "shenqi formula," "shenqi compound formula," "Shen-Qi Compound formula," "Shen-Qi formula.".

Participant or population: Adults patients with an established DM diagnose will be included in our research. There is no limitation about region, sex and age of patient.

Intervention: Studies that use Shenqi Compound(SC) as a major intervention in experimental group will be included.

Comparator: The control group can use any other medicines or placebo. If the authors use combination therapy of SC and other medicines in experimental group, these studies will be excluded.

Study designs to be included: We will only include prospective randomized controlled trials (RCTs).

Eligibility criteria: Adults patients with an established DM diagnose will be included in our research. There is no limitation about region, sex and age of patients.

Information sources: PubMed, Embase, the Cochrane Library Central Register of Controlled Trials, and 4 Chinese databases including China National Knowledge Infrastructure (CNKI) database, Wanfang Data Knowledge Service Platform, the VIP information resource integration service platform (cqvip), China Biology Medicine Disc (Sino Med).

Main outcome(s): Glycosylated hemoglobin(HbA1c);C-reactive protein (CRP);Tumor Necrosis Factor(TNF-α).

Additional outcome(s): Fasting plasma glucose(FPG),Postprandial blood glucose (PBG); Interleukin(IL-6).

Data management: We will import the documents we download from the database into Endnote X8 for Mac (Thomson Reuters) software.

Quality assessment / Risk of bias analysis: The risk of bias of included studies will be assessed by using the Cochrane collaboration's tool. In this tool, the risk of bias of a study is assessed from 7 aspects: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), other bias. Each item is classified as "Low risk," "High risk," or "Unclear risk." If the experimental process is not described in detail in the article, we will contact the authors by E-mail for more methodological information. Two reviewers will conduct the

risk of bias assessment independently and any disagreements will be solved by consensus.

Strategy of data synthesis: 2 methodological trained researchers will screen the qualified articles by reading the title and abstract according to the inclusion the authors or the authors refuse to provide detailed information, then the document will be excluded. For those literature with the same data as another articles, for instance, repeatedly published articles, we will choose the one with more detailed data. For each study, the following information will be extracted: title, the publication country, the first authors of the article, time of publication, baseline information of participants, interventions in experimental group, interventions in control group, time and dose of treatment, course of disease, number of patients in each group, ages and sex of patients, outcomes.

Subgroup analysis: Divided into two subgroups: blood glucose control and inflammatory markers.

Sensibility analysis: To ensure the stability of the results, we will conduct sensitivity analysis of the results by excluding each of the studies included in the analysis one by one, then re-analyzing the results, and comparing the differences between the re-obtained results and the original results. In this way, we will be able to assess the impact of individual studies on overall outcomes and their robustness.

Language: English and Chinese.

Keywords: Shen-qi compound(SC); diabetes; glycemic measures; inflammatory makers; systematic review and meta-analysis.

Contributions of each author:
Author 1 - Yan Yang - Draft manuscript.
Author 2 - Wen Zhong - To provide statistic expertise.
Author 3 - Yuan Tian - To formulate selection criteria.
Author 4 - Hui Zhou - To formulate excluded criteria.