INPLASY PROTOCOL

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This study has no conflicts of interest.

The Effect of Gegen Qinlian Decoction on Clinical Prognosis and Islet Function for Type 2 Diabetic Mellitus: A Protocol for Systematic Review and Meta-analysis

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Review question / Objective: **To systematically assess the effect of Gegen Qinlian Decoction on clinical prognosis and islet function for T2DM patients reported in randomized clinical trials (RCTs).**
Condition being studied: **With the development of social economy, people's lives are improving day by day. Chronic diseases represented by diabetes have gradually entered people's field of vision.At present, about 415 million people in the world suffer from diabetes, of which more than 90% are type 2 diabetes which causes severe physical and mental pain to patients and their families, and also imposes a huge burden on the health care system.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 November 2020 and was last updated on 10 December 2020 (registration number INPLASY2020110083).

INTRODUCTION

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than 90% are type 2 diabetes which causes severe physical and mental pain to patients and their families, and also imposes a huge burden on the health care system.

METHODS

Participant or population: The patients of type 2 diabetes (using WHO 1999 diagnostic criteria). These types of patients will not be included: Patients with severe impairment of islet function; patients with severe diabetic complications; patients with severe liver and kidney lesions; patients with acute cardiovascular and cerebrovascular diseases; poor patient compliance; pregnant or lactating women.

Intervention: According to the conventional diabetes treatment methods recommended by the ADA guidelines, including diet, exercise, and hypoglycemic and lipid-lowering treatments combined with Gegen Qinlian Decoction or modified Gegen Qinlian Decoction.

Comparator: Conventional diabetes treatment recommended by the ADA guidelines and traditional hypoglycemic treatment.

Study designs to be included: We included randomized controlled trials and observational studies : cohort prospective or retrospective, case-control and cross-sectional studies.

Eligibility criteria: Only RCTs (except Quasi RCTs and cluster RCTs) will be included. Animal mechanism studies and non-randomised clinical trials will be excluded. Article that substantially overlaps with another published article in print or electronic media will be excluded. Duplicate publications produced by a single experiment and published as separate papers with different criteria for measuring results, priority will be given to original publications and other publications will be excluded. The language and time of publication will not be restricted.

Information sources: This review was conducted from January 1, 2000 to October 1, 2020, sourced from the Cochrane Library, Pubmed, EMBASE, Science Direct, GOV (Clinical Trials.gov/), European Drug Administration (EMA) (www. ema. europa.eu/ema/), World Health Organization (WHO), International Clinical trial Registration platform (www.wh.int/ICTRP), Web of Science ,Chinese Biomedical Literature(CBM), the China National Knowledge Infrastructure Database (CNKI), Wangfang Database (WF),Chinese Scientific Journal Database (VIP), No limitation on language or publication types restriction will be applied.

Main outcome(s): The primary outcomes include Fasting plasma glucose,2h plasma glucose, Hemoglobin A1c, fasting plasma insulin, insulin resistance index and Insulin secretion index.

Additional outcome(s): The secondary outcomes include clinical efficacy and adverse reactions. The clinical efficacy refers to the guiding principles for clinical research of new Chinese medicines. Significantly effective: symptoms improved significantly more than 70%,the fasting blood glucose is less than 7.0 mmol/L, and the blood glucose 2 hours after a meal is less than 8.3 mmol/L; effective: symptoms reduced by 30% to 70%,and the fasting blood glucose is less than 7.0~9.0 mmol/L ,In the meantime, the blood glucose in 2 hours after meal is between 8.3~10.5 mmol/L; Ineffective: Symptom improvement is less than 30% or no improvement, or even worse, fasting blood glucose is higher than 9.0 mmol/L, and blood glucose 2 hours after meal is higher than 10.5 mmol/L.Total effective rate = (significantly effect+effective)/total number of cases × 100%.Adverse reactions: nausea, abdominal pain, dyspepsia, and dizziness were used as adverse reaction indicators.

Quality assessment / Risk of bias analysis: All the included studies will be assessed based on the guidelines of Cochrane Handbook for Systematic Reviews of Interventions . The evaluation contents include: blindness of participants and personnel, blindness of result evaluation, generation of random sequence,

concealment of distribution, incomplete result data, selective result report and other sources of bias. The quality of each trial will be categorized into three levels: "low bias ", "high bias" and "unclear bias". Any disagreements between the reviewers of both parties will be analyzed by the third-party reviewer and reached an agreement.

Strategy of data synthesis: The risk ratio (RR) of relative risk with 95% confidence interval (CI) was used to summarize the binary results. Continuous results will be summarized by using weighted mean difference (WMD) with 95% CI. According to the research recommendations, we will use the random effects model (REM) for meta-analysis in this paper. Statistical heterogeneity will be evaluated by X^2And I2 statistical tests. When $p \geq 0.1$ and $I2 \leq 50\%$, there is no significant statistical heterogeneity between the studies. On the contrary, the p value 50% indicates a considerable heterogeneity. When the statistical heterogeneity is acceptable (P value ≥ 0.1, I2 ≤ 50%), a meta-analysis will be conducted; otherwise, a subgroup analysis will be conducted to explore the impact of potential factors on the outcome measurement.

Subgroup analysis: According to different races, ages, genders, duration of treatment, and different types of Gegen Qinlian Decoction (intervention forms, drug formulations, dosages, etc.), subgroup analysis will be performed. If meta-analysis is not possible, we will conduct a descriptive analysis.

Sensibility analysis: We will omit studies one by one to conduct sensitivity analysis to explore the impact of individual study.

Language: No limitation.

Country(ies) involved: China.

Keywords: Gegen Qinlian Decoction; Type 2 Diabetes Mellitus; Systematic review.

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