INPLASY PROTOCOL

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There is no conflicts of interest in this review.

Chinese herbal medicine for previous cesarean scar defect: A protocol for systematic review and meta-analysis

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Review question / Objective: **The aim of this systematic review and meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of Chinese medicine for PCSD.**
Condition being studied: **Previous cesarean scar defect (PCSD) is a gynecological disease that can causes bleeding after intercourse, prolonging menstrual period, intermenstrual bleeding, dysmenorrhea and other symptoms, and even lead to infertility. The treatment of this disease includes medicine and surgery, however, single western medicine treatment or surgical treatment has certain and clear shortcomings. In China and East Asia, Chinese medicine has been widespread in the treatment of various diseases for thousands of years. As an important treatment method, Chinese medicine plays an important role in the treatment of gynaecological diseases in China.The aim of this study is to assess the efficacy and safety of Chinese medicine for PCSD.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 September 2020 and was last updated on 22 September 2020 (registration number INPLASY202090080).

INTRODUCTION

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METHODS

Participant or population: Inclusion:1. History of cesarean section; 2. menostaxis >7d; 3. PCSD diagnosed by B-ultrasound or hysteroscopy Exclusion: 1. Menostaxis caused by other reasons (like endocrine diseases, pregnancy, cancer, et al.) 2. Medicine allergy 3. Disobedience or lack of information.

Intervention: Chinese herbal medicine was the main intervention, like Chinese medicine versus Western medicine or Chinese medicine plus Western medicine versus placebo plus Western medicine.

Comparator: Placebo or other therapeutic agents.

Study designs to be included: Randomized controlled trials (RCTs) will be included.

Eligibility criteria: Types of studies. Randomized controlled trials (RCTs) in Chinese and English will be enrolled in this system review. Non-randomized controlled trials (non-RCTs), quasirandomized controlled trials (qRCTs), cohort studies, reviews, experimental studies, expert experience, case reports, the data of the included study is missing or incomplete, and duplicate publications will be excluded. Types of participants. All participants with PCSD will be included regardless of their nationality, occupation, educational background, belief, age, body or race. 2.2.3 Patient and public involvement. This study has no patient and public involvement in consideration of this protocol for a systematic review 2.2.4 Types of interventions. All kinds of Chinese medicine will be included, there are no restrictions on the amounts of herbs, methods of administration, dosage or duration of treatment. The comparsions will be either with other therapeutic agents, or placebo.

Information sources: Other sources. We will search the reference lists of reviews and retrieve articles for additional studies on Google Scholar to identify further studies. We will include the literature published in journals and also "gray literature" such as degree theses and conference proceedings.

Main outcome(s): 1. The size of previous cesarean scar defect 2. Menstrual cycle 3. Menstrual phase 4. Menstrual volume 5. Duration of disease 6. Security index: general physical examination (temperature, pulse, respiration, blood, pressure), routine examination of blood, urine and stool, electrocardiogram, liver and kidney fuction examination.

Quality assessment / Risk of bias analysis: 2 authors will use the Cochrane tool of risk of bias to assess the risk of bias independently. The disagreement will be settled by another reviewer. We will evaluate the following contents: selection bias (random sequence generation, and allocation concealment), performance bias (blinding of participants and personnel), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), reporting bias (selective outcome reporting), and other bias (other sources of bias). Studies will be evaluated high, low and unknown.

Strategy of data synthesis: Relevant literatures will be obtained from the above databases, later imported into a database created by Endnote X8. Duplicate documents will be exclude through this process. And then the 2 review authors will independently scan the titles abstracts and keywords of all articles identified from the electronic databases. Full-text articles will be scanned for all potentially relevant articles. If there is any disagreement on the

selection of the article, it will be discussed with the third author. The selection process will be shown in the Preferred Reporting Items for Systematic Review and Meta-analysis flow chart in Figure 1.

Subgroup analysis: If heterogeneity is detected, subgroup analysis will be performed to explore the differences in the methodologic quality, age, race/ethnicity, and types of Chinese medicine.

Sensibility analysis: Sensitivity analysis will be performed to examine the robustness of the result if there are sufficient studies included. The factors on effect are as follows: methodologic quality: analysis will be performed excluding studies of poor methodologic quality sample size: analysis will be performed excluding small sample size studies diagnostic criteria: analysis will be performed in studies of the same diagnostic criteria.

Country(ies) involved: China.

Keywords: Previous cesarean scar defect, Chinese medicine, protocol, systematic review.

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