INPLASY PROTOCOL

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Review Stage at time of this submission: Risk of bias assessment.

Conflicts of interest: None.

Therapeutic role of Chinese herbal medicine for infertile women with thin endometrium:a systematic review and meta-analysis

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ABSTRACT
Objective: To evaluate the efficacy of Chinese herbal medicine in infertile women with thin endometrium.

Condition being studied: The definition of a thin endometrium varies between studies, but is generally defined as the endometrial thickness below 7 mm on the day of ovulation, the day of HCG administration. It has been demonstrated that endometrium thickness below 7 mm is negatively associated with the chance of pregnancy. Chinese herbal medicine was used to treat thin endometrium and was demonstrated to be effective in increasing the thickness of endometrium and pregnancy rate in some studies.

Information sources: Retrieving CNKI, Wan Fang, Vip, PubMed, EMBASE, Cochrane Library databases, including Chinese and English literature, The search strategy consisted with the following terms: "(thin endometrium)" and"(infertile women) or(infertility)or(female infertility)or(sterility)"and"(Chinese herbal medicine)or(traditional Chinese medicine)or(Chinese medicine)or(herbs)or(complementary or alternative medicine)". All searches ended in September 2019.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 April 2020 and was last updated on 02 April 2020 (registration number INPLASY202040007.

INTRODUCTION

Objectives / Review question: To evaluate the efficacy of Chinese herbal medicine in infertile women with thin endometrium.

Condition being studied: The definition of a thin endometrium varies between studies, but is generally defined as the endometrial thickness below 7 mm on the day of ovulation, the day of HCG administration. It has been demonstrated that endometrium thickness below 7 mm is negatively

associated with the chance of pregnancy. Chinese herbal medicine was used to treat thin endometrium and was demonstrated to be effective in increasing the thickness of endometrium and pregnancy rate in some studies.

METHODS

Participant or population: Inclusion: women with a history of the maximal endometrial thickness below 7 mm on the day of ovulation, the day of HCG administration. Exclusion: patients suffered from other diseases besides thin endometrium.

Intervention: Intervention measures: Chinese herbal medicine(CHM) interventions that will be accepted for this review are oral administrations and which can contain one or multiple herbs within the preparation. Acceptable oral administrative forms are decoction, powder, liquid or capsule/pill. Non-oral administration methods will be excluded.

Comparator: Included control group (no treatment or placebo or Western medicine), CHM were used in the experimental group.

Study designs to be included: We will include randomised trials, cohort studies and case-control studies.

Eligibility criteria: In this review, only randomized controlled trials (RCTs) evaluating CHM for infertile women with thin endometrium were eligible for inclusion, regardless of publication status or language. Quasi-RCTs were excluded, such as allocation by medical record number, visiting sequence, and date of birth. Baseline assessments were necessary.

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Main outcome(s): Endometrial thickness; clinical pregnancy rate.Measures of effect：Menstrual cycle medication Change in menstrual rate from baseline to last available follow-up.

Additional outcomes: The secondary outcome indicators were embryo transfer rate, live birth rate and menses amounts.

Quality assessment / Risk of bias analysis: Using the Cochrane risk of bias assessment tool (www.cochrane-handbook.org) to assess: selection bias (random sequence generation and allocation concealment); performance bias (blinding of participants and personnel); detection bias (blinding of outcome assessors); attrition bias (incomplete outcome data); reporting bias (selective reporting); and other sources of bias. Any disagreements were resolved by discussion.

Strategy of data synthesis: A network meta-analysis will draw on both direct evidence and indirect evidence, with the benefit of randomization in each study retained. For indirect and direct evidence to be consistent, population and intervention characteristics must be similar across comparisons. Inconsistency between direct and indirect evidence will be assessed using the node-splitting method. The SMD will be assumed to be normally distributed and a random-effects network meta-analysis model will be selected. Analyses will be conducted using Stata and RevMan software.

Subgroup analysis: None planned.

Sensibility analysis: For binary data, the results of each study were expressed as a 95% confidence interval risk ratio (RR).For continuous data, standardized mean difference (SMD) is calculated.Since all included studies used different Chinese

herbs, heterogeneous results were inevitable.Therefore, the random effect method is used as a prior method to calculate the total effect.

Language: China.

Keywords: thin endometrium; infertility; Chinese herbal medicine; Meta-analysis; Systematic review.

Contributions of each author:

Author 1 - Fenghua(FH)initiated the study and participated in its design,database search,study selection, data extraction and drafting the manuscript.

Author 2 - Huifang Zhou(ZHF)developed the research design and supervised all aspects of the study.

Author 3 - Yujie Shang(SYJ)participated in the study design and helped to search databases extract and assess studies and draft the manuscript.