

INPLASY PROTOCOL

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There are no conflicts of interest.

A Comparison of the Efficacy and safety of traditional Chinese medicine in preconditioning patients with diminished ovarian reserve that would undergo In Vitro Fertilization: A network meta-analysis protocol

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Review question / Objective: Population: Those women preconditioned by traditional Chinese medicine with diminished ovarian reserve (DOR) before In Vitro Fertilization (IVF); Intervention: Chinese medicine decoction or Chinese patent medicine should be used, acupuncture, massage and other external treatments were excluded. Comparison: without traditional Chinese medicine. Outcome: The effectiveness and safety of TCM in preconditioning women with DOR that would undergo IVF.

Condition being studied: DOR prevalence increased quickly in recent years especially in those women that would undergo IVF, the treatment way was limited and couldn't achieve ideal effects, but some TCM study reported good outcome.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 November 2020 and was last updated on 16 November 2020 (registration number INPLASY2020110062).

INTRODUCTION

Review question / Objective: Population: Those women preconditioned by traditional

Chinese medicine with diminished ovarian reserve (DOR) before In Vitro Fertilization (IVF); Intervention: Chinese medicine decoction or Chinese patent medicine

should be used, acupuncture, massage and other external treatments were excluded. Comparison: without traditional Chinese medicine. Outcome: The effectiveness and safety of TCM in preconditioning women with DOR that would undergo IVF.

Rationale: A number of TCM study reported good outcome in dealing with DOR in those women that would undergo IVF, The conclusions were not entirely consistent, so a meta-analysis is necessary now.

Condition being studied: DOR prevalence increased quickly in recent years especially in those women that would undergo IVF, the treatment way was limited and couldn't achieve ideal effects, but some TCM study reported good outcome.

METHODS

Search strategy: A comprehensive literature search will be conducted in three English and five Chinese electronic databases, including the Cochrane library, PubMed, EMBASE, WanFang Database, China National Knowledge Infrastructure, VIP Database, Chinese Biomedical Database and Chinese Clinical Trial Register to Search papers published in recent five years. We will apply a combination of Medical Subject Heading (MeSH) and free-text terms to implement search strategies.

Participant or population: Those women preconditioned by traditional Chinese medicine with diminished ovarian reserve (DOR) before In Vitro Fertilization (IVF).

Intervention: Chinese medicine decoction or Chinese patent medicine should be used, acupuncture, massage and other external treatments were excluded.

Comparator: Without traditional Chinese medicine.

Study designs to be included: Published randomized controlled trials (RCTs), Case-control studies and cohort studies evaluating the role of TCM (Not

acupuncture) in treating women with DOR that would taken in IVF were eligible for inclusion.

Eligibility criteria: We will exclude studies in which DOR was induced by unilateral or bilateral ovary removal surgery, chromosome abnormality, participants included which were diagnosed with premature ovarian failure (POF) or primary ovarian insufficiency (POI) and those Studies without clear diagnostic criteria. IVF intervenes or full texts were also considered ineligible for this analysis.

Information sources: Published randomized controlled trials (RCTs), Case-control studies and cohort studies in three English and five Chinese electronic databases, including the Cochrane library, PubMed, EMBASE, WanFang Database, China National Knowledge Infrastructure, VIP Database, Chinese Biomedical Database and Chinese Clinical Trial Register will be included in this study, we will contact the author if there are questions by e-mail or telephone.

Main outcome(s): We will evaluate the efficacy and safety of TCM, basal serum FSH level, basal serum E2 level, FSH/LH ratios, AMH level, AFC, high quality embryo ratios and pregnancy ratios will be compared in these studies.

Additional outcome(s): No.

Data management: Two researchers independently undertake the search. All studies identified from electronic searches will be imported into Endnote literature management software (X9). duplications will be eliminated. Evidently irrelevant studies will be excluded by reading the title and abstract of all articles, then the full texts of the remaining studies will be retrieved and assessed against our predefined inclusion criteria. Advice from a third reviewer will be sought whenever disagreement arose between the two researchers.

Quality assessment / Risk of bias analysis:

Two of us will assessed the quality of included studies independently using the Cochrane risk of bias assessment tool. The results included the following domains: random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessors, incomplete outcome data, selective reporting, and other sources of bias. An assessment of risk of bias will be made for the eligible studies based on the following three levels: “low risk of bias” “unclear risk of bias” “high risk of bias” by using information identified from the published articles and by contacting the authors when needed.

Strategy of data synthesis: We used Review Manager5.3, provided by the Cochrane collaborations, for data analysis. We will assess heterogeneity across trials to decide whether it is meaningful to have the data pooled by using the I² statistic . I² ≤ 50% means moderate heterogeneity ,it could be accepted ; I² > 50% means notable heterogeneity, original studies were reviewed to check the raw data and the methods used were correct and identify some possible causes in that case,A random-effect model would be used if the variation could not be explained.

Subgroup analysis: If heterogeneity is found in the included literature, it will be resolved by subgroup analysis.

Sensibility analysis: We will conduct a sensitivity analysis to guarantee the robustness of the review conclusions, methodological quality, sample size, and the effect of missing data.

Language: We will search all reports in English and Chinese.

Country(ies) involved: China.

Other relevant information: No.

Keywords: Diminished Ovarian Reserve, IVF, Meta Analysis, TCM, precondition.

Contributions of each author:

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