INPLASY PROTOCOL

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The authors have no conflict of interests to disclose.

Efficacy and safety evaluation of acupuncture therapy for patients with salpingitis in IVF-ET. A protocol of systematic review and meta-analysis

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Review question / Objective: **As an alternative for salpingitis in IVF-ET, acupuncture has gradually attracted the attention of clinicians based on the theory of syndrome differentiation and treatment of Chinese traditional medicine. However, due to the lack of evidence-based medical evidence, the author designed the program to evaluate the effectiveness and safety of acupuncture. From the beginning to August 2020, 8 electronic databases will be searched. Two of our researchers will independently conduct research selection, data extraction, and risk assessment of bias. We will use Review Manager 5.3 software for meta-analysis and heterogeneity assessment. In addition, we will use the grading of recommendations assessment, development, and evaluation to evaluate the evidence quality. This study will demonstrate an evidence-based review of acupuncture of traditional Chinese medicine for salpingitis in IVF-ET, and we will provide clear evidence to assess the effectiveness and side effects of acupuncture for salpingitis in IVF-ET.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 November 2020 and was last updated on 28 November 2020 (registration number INPLASY2020110125).

INTRODUCTION

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Condition being studied: Salpingitis can lead to hydrosalpinx, adhesion, and even blockage, which is also the main reason for female infertility. Therefore, more and more people are in need of assisted reproductive treatment worldwide.IVF-ET provides an effective treatment method for successful pregnancy of infertility. Salpingitis may cause secondary inflammation of endometrium and pelvis, and will have a lasting and significant impact on IVF-ET. Therefore, in IVF-ET, the treatment of salpingitis is also an important step.Acupuncture has been proved to be effective in improving the success rate of IVF-ET. however, the safety and effectiveness of acupuncture in the treatment of salpingitis in IVF-ET are still unclear.So we will organize, analyze, summarize studies that we could find on all databases about acupuncture for salpingitis in IVF-ET to provide a clear and significant evidence for clinicians.

METHODS

Participant or population: All participants were clinically diagnosed with salpingitis in IVF-ET, without restrictions on the TCM classification of salpingitis in IVF-ET, such as age, sex, disease duration, and race. But some special patients will not be included even if they meet the clinical criteria for UC, such as pregnant or nursing women, people with severe heart, liver or lung disease, those with the history of major trauma surgery.

Intervention: Acupuncture is used alone or in combination with other treatment methods. The types of Acupuncture of TCM and methods of combination will be ignored.

Comparator: Other treatments (including any other non- Chinese medicine treatment) or combined with fake Chinese medicine.

Study designs to be included: Only randomized controlled trials will be included.

Eligibility criteria: We will only include randomized controlled trials (RCTs) of acupuncture for salpingitis in IVF-ET, regardless of reviews, protocols, animal experiments, case studies, non-therapeutic clinical studies.

Information sources: We will search 7 databases, including 4 Chinese databases: VIP, Wanfang, CNKI, and the Chinese Biomedical Literature Database (CBM), and 3 English databases: the Web of Science, Pubmed, and Embase databases.

Main outcome(s): The improvement of clinical symptoms (such as fever, abdominal tenderness or rebound pain, uterine and accessory tenderness, cervical lifting pain, etc) should be improved within 3 days after the treatment; the pregnancy rate after treatment should be more than 65% . The total effectiveness rate is a percentage, which is the ratio of the sum of the number of mitigators and effective people to the total number.

Quality assessment / Risk of bias analysis: Two researchers will evaluate the quality of RCTs by using the risk assessment tool recommended in Cochrane Handbook 5.3. This evaluation includes 6 factors: generation of random sequences, blinding of investigators and participants, blinding of study results, completeness of outcome data, selectivity in reporting of results, and other biases. If there are missing or unclear data, we will attempt to contact the original authors by email. If no reply is received or the authors have not saved the original

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data, we will analyze only the data that are useful in the literature or analyze the missing data in the discussion.

Strategy of data synthesis: This study involves bicategorical and continuous variables. The relative risk (RR) is used as an effect measure in the bicategorical variables and the mean differences (MD) in the continuous variables, and the software is able to obtain the point estimates and the 95% confidence interval (CI) for the 2. I2 is an important index for making the heterogeneity judgment. If I2 < 50%, a fixed effects model is used; if I2 ≧ 50%, a random effects model is used. For each combined analysis, the test of heterogeneity is measured using the cardinality statistic.

Subgroup analysis: If I2 ≧ 50%, substantial heterogeneity is considered to be present. If heterogeneity is present, we will analyze the cause through subgroup analysis.

Sensibility analysis: If heterogeneity is present, we will analyze the cause through sensitivity analysis.

Country(ies) involved: China.

Keywords: salpingitis, in vitro fertilization and embryo transfer, meta-analysis, protocol, systematic review, acupuncture.

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