INPLASY PROTOCOL

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Review Stage at time of this submission: The review has not yet started.

Conflicts of interest: None declared.

INTRODUCTION

Review question / Objective: Types of participants: PCOS patients with clear diagnostic criteria. Types of interventions and comparators: The intervention group received traditional acupuncture or acupuncture combining with other treatment methods, while the control group received sham acupuncture or placebo

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 April 2021 and was last updated on 03 April 2021 (registration number INPLASY202140015).

> drugs or Western medicine. Types of studies: The selected articles should be Randomized Controlled Trials (RCT) and Clinical Controlled Trials (CCT) Types of outcomes: The primary outcomes are ultrasonographic (endometrial thickness, endometrial type, endometrial volume, uterine artery blood flow), and the secondary outcomes are sex hormones,

Efficacy of Acupuncture on PCOS endometrial receptivity: a protocol for systematic review and meta analysis

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Condition being studied: Polycystic ovary syndrome (PCOS) is an endocrine disorder syndrome characterized by persistent anovulation, high androgens, hyperinsulinemia (HA) and Insulin resistance (IR), and its incidence is as high as 20% in women of reproductive age. The main treatment of PCOS is the ovulation stimulant clomiphene, however, the use of clomiphene often results in patients with endometrium thinning. The high hormone status of PCOS patients will also reduce the endometrial receptivity, leading to endometrial growth disorder, resulting in the secondary endometrial thin and decreased endometrial receptivity, which is an important mechanism for the decrease of pregnancy rate in PCOS patients. Therefore, from the perspective of improving endometrial thickness and endometrial receptivity, it has become an urgent key to try to find an auxiliary method that can improve pregnancy rate of PCOS patients. Acupuncture and moxibustion treatment of PCOS in traditional medicine has a long history, which is safe, economical and with remarkable efficacy. Zhang Weiyi ET al. believed that acupuncture can significantly improve the poor endometrial receptivity caused by ovulation induction induced by clomiphene (CC) by regulating the expression of molecular protein and mRNA which are markers of endometrial receptivity, thus increasing the success rate. Zhu Xiudu et al. showed that compared with clomiphene (CC), the application of acupuncture in the treatment of PCOS has a high cure rate, high pregnancy rate and low abortion rate, and has a particularly good effect on the improvement of endocrine function and endometrial receptivity. In addition, more and more clinical trials have been published, and acupuncture is becoming more widely used internationally. It is necessary to update and supplement the systematic review of the endometrial receptivity of PCOS. Therefore, we decided to conduct an evidence-based review to evaluate the efficacy and safety of acupuncture on endometrial receptivity of PCOS.

METHODS

Participant or population: PCOS patients with clear diagnostic criteria.

Intervention: The intervention group received traditional acupuncture or acupuncture combining with other treatment methods.

Comparator: The control group received sham acupuncture or placebo drugs or Western medicine.

Study designs to be included: The selected articles should be Randomized Controlled Trials (RCT) and Clinical Controlled Trials (CCT).

Eligibility criteria: Types of participants: PCOS patients with clear diagnostic criteria. Types of interventions and comparators: The intervention group received traditional acupuncture or acupuncture combining with other treatment methods, while the control group received sham acupuncture or placebo drugs or Western medicine. Types of studies: The selected articles should be Randomized Controlled Trials (RCT) and Clinical Controlled Trials (CCT) Types of outcomes: The primary outcomes are ultrasonographic (endometrial thickness, endometrial type, endometrial volume, uterine artery blood flow), and the secondary outcomes are sex hormones, BMI, pregnancy outcome, adverse reactions, etc.

Information sources: Comprehensive retrieval databases include the following databases :Cochrane Library, PubMed, EMbase; Chinese Academic Journal Fulltext Database (CNKI), Chinese Biomedical Literature Database (CBMdisc), Weipu Chinese Science and Technology Journal Full-text Database (VIP), Wanfang Data Knowledge Service Platform (Wanfang), the time limitation is from the construction of the library to September 2019. We will develop a corresponding search strategy under the guidance of the cochrane search guide. The relevant meeting records, trial registers, and a reference list of publications identified will also be searched for further trials. The following group terms will be used for searching (Acupuncture OR Acupuncture Therapy OR Acupuncture, Ear OR Acupuncture Points OR Acupuncture Analgesia) AND (PCOS OR Polycystic ovary syndrome OR Ovary Syndrome, Polycystic OR Syndrome, Polycystic Ovary).

Main outcome(s): Ultrasonographic (endometrial thickness, endometrial type, endometrial volume, uterine artery blood flow).

Additional outcome(s): Sex hormones, BMI, pregnancy outcome, adverse reactions, etc.

Quality assessment / Risk of bias analysis:

The Cochrane risk bias assessment tool will be used to evaluate the methodological quality of the included literature: including random methods, allocation hiding methods, blind methods, baselines, intentionality analysis, number of missing follow-ups, and reasons for withdrawal, and the quality of the literature was classified as A (Less bias), B (medium bias), C (high bias). The literature included in the evaluation will be independently evaluated by 2 reviewers in the research team, and in case of disagreement, a third reviewer will participate in the discussion and settlement.

Strategy of data synthesis: Endnote X9.0 will be used to manage the retrieved studies. Preliminary screening involves reading titles and abstracts to eliminate duplicates and ineligible studies. Rescreening involves reading the full text and selecting studies based on inclusion and exclusion criteria. Differences between the two reviewers will be resolved through discussion, with a third reviewer consulted if necessary. Two reviewers will independently screen the titles, abstracts, and keywords of the retrieved studies and further assess the full texts. Excluded studies were recorded with explanations. Two reviewers will independently extract the data and complete the predefined data extraction form. General information, participants, methods, interventions, outcomes, results, adverse events, conflicts of interest, ethical approval, and other information will be extracted. Disagreements will be solved by discussion between the two reviewers and arbitrated by the third reviewer when necessary. Authors of the studies will be contacted for clarification and missing data.

Subgroup analysis: Subgroup analysis will be performed based on the results of data synthesis if the heterogeneity is high. The following subgroup analyses will be considered: intervention methods (type, time) and measures used in clinical trials.

Sensitivity analysis: XChoose different statistical models (FE / RE) for metaanalysis of outcome indicators, and evaluate the combined effect. If there is no substantial change in the results before and after the sensitivity analysis, the metaanalysis results are more credible; if the sensitivity analysis results are significantly different, it indicates that the meta-analysis results are less robust, that is, there are potential other factors related to the effect of the intervention, Therefore, the interpretation of the results should be more conservative.

Country(ies) involved: China.

Keywords: Acupuncture; Polycystic ovary syndrome; Endometrial Receptivity; Meta analysis; Protocol.

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