

INPLASY PROTOCOL

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**Review Stage at time of this
submission:** Data analysis.

Conflicts of interest:
None declared.

INTRODUCTION

Review question / Objective: The purpose of this study was to investigate the difference between the efficacy of traditional Chinese medicine formulas

Effectiveness of Combination of Chinese medicinal formulas and acupuncture for Anovulatory infertility: A Systematic Review and Meta-Analysis

Mo, JW¹; Zhang, YY²; Jin, N³; Zhou, Y⁴.

Review question / Objective: The purpose of this study was to investigate the difference between the efficacy of traditional Chinese medicine formulas combined with acupuncture in the treatment of ovulation dysfunction infertility and that of drug therapy alone, and the selected research method was RCT experiment.

Condition being studied: Ovulation disorder is caused by ovarian ovulation dysfunction due to some reasons and failure to ovulate, which affects the combination of sperm and egg, the formation of infertility. This is one of the important factors leading to female infertility. Treatment is mainly to promote ovulation drugs, strengthen the luteal function and so on. In recent years, there have been more and more clinical reports on acupuncture combined with traditional Chinese medicine in the treatment of infertility due to ovulation disorder, but there is still no strong evidence on its effectiveness.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 March 2023 and was last updated on 12 March 2023 (registration number INPLASY202330040).

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METHODS

Participant or population: Patients with clear diagnosis of ovulation dysfunction infertility, from any source. Western medicine diagnostic criteria: refer to the diagnostic criteria of Obstetrics and Gynecology or European Reproductive Society; Chinese medicine diagnostic criteria: "Guidelines for Clinical Research on New Chinese Medicines "Gynecology of Chinese Medicine". There will be no restriction on race, nationality or education level.

Intervention: Chinese medicine formulas combined with acupuncture.

Comparator: Medicine.

Study designs to be included: Primary outcome indicators: effective rate, pregnancy rate, endometrial thickness. Secondary outcome indicators: basal body temperature recovery rate, ovulation rate, maximum follicle diameter.

Eligibility criteria: Patients with a clear diagnosis of ovulatory infertility, from any source. Western medicine diagnostic criteria: refer to the diagnostic criteria of Obstetrics and Gynecology or European Reproductive Society; Chinese medicine diagnostic criteria: "Guidelines for Clinical Research on New Chinese Medicines" or "Gynecology of Chinese Medicine". There will be no restriction on race, nationality or education level. 1.1.5 Exclusion criteria

(i) duplicate publications; (ii) incorrect or unavailable data; (iii) serious primary diseases such as cardiovascular disease; (iv) other factors associated with infertility, such as organic lesions of reproductive organs.

Information sources: Computer searches of PubMed, EMBase, The Cochrane Library, CNKI, WanFang Data, CBM, and VIP databases were conducted to collect RCTs of traditional Chinese medicine formulas combined with acupuncture for the treatment of ovulatory disorders of infertility, all with a search time frame of build to March 12, 2023. Searches are conducted using combination of subject terms and free words, and are adjusted to the characteristics of each database. References of included studies were also searched to supplement access to relevant literature. Search terms included: ovulation disorders, infertility, acupuncture, electroacupuncture, auricular acupuncture, acupuncture point injection, traditional Chinese medicine, Chinese medicine.

Main outcome(s): Effective rate, pregnancy rate, endometrial thickness.

Additional outcome(s): Basal body temperature recovery rate, ovulation rate, maximum follicle diameter.

Quality assessment / Risk of bias analysis: The risk of bias was evaluated using the RCT risk of bias assessment tool recommended in Cochrane Handbook 5.4.0.

Strategy of data synthesis: RevMan 5.4 software was used for statistical analysis, and the relative risk ratio (RR) and 95% CI were used for counting data and weighted mean difference (WMD) was used for measurement data to calculate effect sizes. The χ^2 test was used to test the heterogeneity among the studies at the level of $\alpha=0.1$, and then the degree of heterogeneity was estimated according to the I^2 value: $I^2 < 40\%$ suggested that there was no significant statistical heterogeneity, and the fixed-effect model was selected for

the combined analysis; 405% suggested substantial heterogeneity, and the combined analysis was not advocated. If the literature was adequate, funnel plot analysis for publication bias was performed. Intention-to-treat (ITT) analysis was performed on incomplete data to further validate the reliability of the evidence.

Subgroup analysis: No.

Sensitivity analysis: No.

Country(ies) involved: China.

Keywords: Acupuncture; Ovulatory disorders; traditional Chinese medicine; Infertility; Systematic evaluation; Meta-analysis; Randomized controlled trial.

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