INPLASY

Meta-Analysis of Traditional Chinese Medicine Cyclic Therapy for Infertility in Polycystic Ovary Syndrome

INPLASY2024120001

doi: 10.37766/inplasy2024.12.0001

Received: 1 December 2024

Published: 1 December 2024

Lin, S; Zhou, S.

Corresponding author:
Shaoqiao Lin

942572654@qq.com

Author Affiliation:
Guangzhou Nansha district wanqingsha town community health service center.

ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2024120001

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 1 December 2024 and was last updated on 1 December 2024.

INTRODUCTION

Review question / Objective Disease type: Polycystic Ovary Syndrome (PCOS)-related infertility, Intervention: Traditional Chinese Medicine (TCM) cyclic therapy, Control intervention: Clomiphene citrate, Outcome measures: FSH (Follicle-Stimulating Hormone), LH (Luteinizing Hormone), T (Testosterone), E2 (Estradiol), PRL (Prolactin), LH/FSH ratio, ovulation rate, pregnancy rate, endometrial thickness. Study type: Randomized Controlled Trial (RCT).

Condition being studied Infertility refers to the inability to conceive after at least one year of marriage, with regular sexual intercourse and without using any contraceptive measures. Polycystic ovary syndrome (PCOS) is a condition characterized by ovulatory dysfunction, hyperandrogenemia, and polycystic ovaries, with the primary clinical manifestations including menstrual irregularities, infertility, hirsutism, facial acne, and obesity.

METHODS

Search strategy An author systematically searched several databases, including PubMed, Embase, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), Wanfang, China Scientific Journal Database (VIP) and China Biomedical Database (CBM), and conducted related research from their beginning to December 1, 2024. In addition, China Clinical Trial Registry was consulted to determine qualified, ongoing and/or unpublished trials. Search parameters are limited to articles published in Chinese or English.

Search strategy：

Type of disease：Polycystic Ovary Syndrome with Infertility, Intervention measure：“periodic therapy of traditional Chinese medicine”[Title/Abstract] OR “TCM menstrual cycle therapy”[Title/Abstract] OR “TCM Menstrual Regulation Therapy”[Title/Abstract] OR “TCM Menstrual Cycle Adjustment Therapy” Research type：“randomized controlled

trial" [Publication Type] OR"randomized" [Title/Abstract] OR"placebo"[Title/Abstract].

Participant or population Infertility patients with polycystic ovary syndrome.

Intervention Traditional Chinese Medicine Cyclic Therapy.

Comparator Clomiphene or letrozole treatment.

Study designs to be included Study design to be included:We will include the following types of studies: randomized controlled trials.We will be included in the study of infertile patients with polycystic ovary syndrome.Intervention measures: We will compare the therapeutic effect of clomiphene citrate or letrozole and Chinese medicine cycle therapy on polycystic ovary syndrome infertility.Main outcome measures include FSH, LH, T, E2, PRL, LH/FSH, ovulation rate, pregnancy rate and endometrial thickness.Data synthesis strategy: Review Manager version 5.3.3 and Stata Release version 16.0 were used for meta-analysis.

Eligibility criteria Inclusion criteria: Meeting the diagnostic criteria for infertility associated with polycystic ovary syndrome (PCOS); RCT (Randomized Controlled Trial); Interventions: The treatment group receives traditional Chinese medicine (TCM) cyclic therapy, while the control group receives clomiphene citrate; (4) At least one of the following outcome measures must be included: ovulation rate, pregnancy rate, FSH (Follicle-Stimulating Hormone), LH (Luteinizing Hormone), T (Testosterone), E2 (Estradiol), PRL (Prolactin), endometrial thickness, number of mature follicles, and BBT (Basal Body Temperature).
Exclusion criteria: Duplicate publications; studies with self-controlled pre-post designs and non-RCT (Randomized Controlled Trial) literature; studies combining other non-pharmacological treatment modalities.

Information sources CNKI、VIP、Wanfang database、SinoMed、Cochrane library、embase、pubmed、web of science.

Main outcome(s) FSH, LH, T, E2, PRL, LH/FSH, ovulation rate, pregnancy rate and endometrial thickness.

Additional outcome(s) None.

Quality assessment / Risk of bias analysis For randomized controlled trials, we will use Cochrane risk bias tool to evaluate. We will evaluate the quality of each study according to the following criteria: random sequence generation, distributed hidden blindness (including the blindness of participants, researchers and outcome evaluators), incomplete result data, selective reporting of other potential sources of bias (such as sources of funds, conflicts of interest, etc.). Evaluation process: two independent evaluators will evaluate the quality of each study, and any differences will be resolved through discussion or third-party arbitration. Classification of biased risks: According to the results of evaluation tools, the research is divided into "low risk", "high risk" or "uncertain risk". Report the results of quality assessment: We will report the results of quality assessment in detail in the final system assessment report, including marking the risk level of bias in forest maps or other graphics. The influence of bias on the interpretation of results: We will discuss the possible influence of quality evaluation results on the research conclusions and explain these results.

Strategy of data synthesis Use Review Manager version 5.3.3 and Stata Release version 16.0 for meta-analysis. Calculate the relative risk (RR) of binary variables and the corresponding 95% confidence interval (95% CI). Continuous data is expressed as standardized mean difference (SMD), corresponding to 95% confidence interval. Heterogeneity was evaluated by q test and I statistics. P value < 0.1 or I value ≥ 50% indicates the heterogeneity of the research results. After detecting heterogeneity, the meta-analysis uses random effect model to conduct sensitivity and subgroup analysis to determine the source of heterogeneity. The fixed effect model is used without significant heterogeneity. Use Review Manager version 5.3.3 and Stata Release version 16.0 for meta-analysis. Calculate the relative risk (RR) of binary variables and the corresponding 95% confidence interval (95% CI). Continuous data is expressed as standardized mean difference (SMD), corresponding to 95% confidence interval. Heterogeneity was evaluated by q test and I statistics. P value < 0.1 or I value ≥ 50% indicates the heterogeneity of the research results. After detecting heterogeneity, the meta-analysis uses random effect model to conduct sensitivity and subgroup analysis to determine the source of heterogeneity. The fixed effect model is used without significant heterogeneity.

Subgroup analysis This system evaluation does not include subgroup analysis.

Sensitivity analysis After excluding any single study, the remaining literatures were used for meta-analysis. If the results were consistent with the original meta-analysis and the funnel diagram was symmetrical, the test results of Egger (P>0.05) showed that there was no significant publication bias, indicating that the research results were stable and reliable. If the funnel diagram is asymmetric, the cutting and patching method is adopted.

Language restriction We only search Chinese and English documents.

Country(ies) involved China/Guangzhou Nansha district wanqingsha town community health service center.

Other relevant information None.

Keywords Traditional Chinese Medicine Cyclic Therapy,Patients with Polycystic Ovary Syndrome and infertility.

Contributions of each author

Author 1 - Shaoqiao Lin - Responsible for research and design, data collection, formal analysis and final review of the manuscript. Guangzhou Nansha district wanqingsha town community health service center.
Email: 942572654@qq.com
Author 2 - Shanshan Zhou - Participate in data collection, formal analysis, verification of analysis results and drafting of original manuscripts. Zhuhai Xiangzhou District People's Hospital.
Email: 1437805101@qq.com