INPLASY PROTOCOL

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None declared.

The Comparision of Impact of Chinese Medicine and Diane-35 on Sex Hormone Level in Adolescent with Polycystic Ovary Syndrome

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Review question / Objective: **The Comparision of Impact of Chinese Medicine and Diane-35 on Sex Hormone Level in Adolescent with Polycystic Ovary Syndrome.**
Condition being studied: **Adolescent patients who met the diagnostic criteria of PCOS.**
Information sources: **English databases (PubMed, Embase, Web of Science, and the Cochrane Library) and Chinese databases (China National Knowledge Infrastructure(CNKI), Wanfang, the China Science and Technology Journal Database (VIP), and the Chinese Biomedical Literature Database (CBM)).**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 November 2022 and was last updated on 08 November 2022 (registration number INPLASY2022110031).

INTRODUCTION

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METHODS

Participant or population: **Adolescent patients who met the diagnostic criteria of PCOS, using the 2003 Rotterdam criteria by European Society for Human Reproduction (ESHRE) and American Society for Reproduction (HSRM), 2011 PCOS diagnostic criteria by the endocrinology**

group of the Obstetrics and Gynecology Branch of the Chinese Medical Association.

Intervention: The experimental group was only administered Chinese herbal decoctions and there were no restrictions on the herbal composition, dosage, frequency of intake in a day in the included RCTs. All the patients received treatments for 3 cycles.

Comparator: The control group was treated with Diane-35, taking one tablet orally every day for 21 days from the fifth day of menstruation.All the patients received treatments for 3 cycles.

Study designs to be included: Randomized controlled trials (RCTs) published in Chinese and English that used Chinese medicine to treat PCOS patients comparing with Diane-35.

Eligibility criteria: (1) duplicate publications; (2)RCTs on animal studies;(3)no target outcomes; (4) missing data and unable to contact the investigator.

Information sources: English databases (PubMed, Embase, Web of Science, and the Cochrane Library) and Chinese databases (China National Knowledge Infrastructure(CNKI), Wanfang, the China Science and Technology Journal Database (VIP), and the Chinese Biomedical Literature Database (CBM)).

Main outcome(s): The main outcome indicators in this study included the serum level of 5 sex hormones: testosterone(T), estradiol (E2), prolactin (PRL), follicle stimulating hormone (FSH), luteinizing hormone (LH), and the rate (LH/FSH) . In addition, safety was measured based on adverse effects.

Quality assessment / Risk of bias analysis: The Risk of Bias Assessment Tool recommended by the Cochrane Collaboration was used to assess the risk of bias of the included RCTs. 7 aspects were inclued: (1) random sequence generation method; (2)allocation protocol concealment; (3)blindness to subjects and intervention providers; (4)blindness to outcome assessors; (5) completeness of outcome data; (6) selective reporting of study results; (7)other biases. “High risk,” “low risk,” and “unclear risk” were assessed for each aspect. Any different opinions between the two researchers were referred to a third researcher for adjudication.

Strategy of data synthesis: RevMan 5.4 software was used for metaanalysis. Dichotomous variables were expressed with the response ratio (RR), and the continuous variables were expressed using mean differences (MD). The $\chi 2$ test was performed for heterogeneity. If $p > 0.1$ and $I2 < 50\%$, the heterogeneity among RCTs was low and the fixed effect model (FEM) was used for meta-analysis; while if $p < 0.1$ and $I2 \geq 50\%$, the heterogeneity was statistically significant and the random effect model (REM) was used for the meta-analysis.

Subgroup analysis: The possible reasons for heterogeneity were analyzed by subgroup analysis, which items included different ages, duration of the disease and CM therapeutic principles.

Sensitivity analysis: Sensitivity analysis was performed for each outcome to assess stability.

Country(ies) involved: China.

Keywords: Chinese Medicine, Diane-35 , sex hormone, adolescent, PCOS.

Contributions of each author:

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