INPLASY PROTOCOL

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

Conflicts of interest:
None.

Efficacy of clomifene citrate combined Bushen Culuan Decoction for the treatment of infertility caused by polycystic ovary syndrome: a protocol of systematic review

Feng, J[1]; Zhang, XF[2]; Ren, JN[3]; Huang, YH[4]; Zheng, X[5].

Review question / Objective: **Does clomifene citrate combined Bushen Culuan Decoction (CCBCD) effectively treat infertility caused by polycystic ovary syndrome (PCOS)?**
Condition being studied: **Polycystic ovary syndrome; infertility; clomifene citrate; Bushen Culuan Decoction.**
Information sources: **We will search electronic databases in Cochrane Library, PUBMED, EMBASE, Web of Science, CINAHL, and China National Knowledge Infrastructure from inception to the present. These databases will be searched for eligible RCTs published without restrictions to the language and publication time. The detailed search strategy of Cochrane Library is provided. Similar search strategies will be modified for other electronic databases. In addition, we will retrieve other sources, such as conference abstracts, ongoing or unpublished studies from clinical trial registry, and reference lists of associated reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 May 2020 and was last updated on 24 May 2020 (registration number INPLASY202050090).

INTRODUCTION

Review question / Objective: **Does clomifene citrate combined Bushen Culuan Decoction (CCBCD) effectively treat infertility caused by polycystic ovary syndrome (PCOS)?**

Condition being studied: **Polycystic ovary syndrome; infertility; clomifene citrate; Bushen Culuan Decoction.**

METHODS

Participant or population: All eligible female adults (aged more than 18 years old) who were diagnosed as PCOS will be included, regardless race, country, and duration of PCOS.

Intervention: All eligible patients in the interventional group received CCBCD.

Comparator: All eligible participants in the control group received any treatment. However, we will exclude patients who also underwent any forms of CC, Bushen Culuan Decoction, or CCBCD.

Study designs to be included: This study includes randomized controlled trials (RCTs) of CCBCD in treating PCOS. We will exclude all non-RCTs, such as review, non-clinical trials.

Eligibility criteria: This study includes RCTs of CCBCD in treating PCOS. We will exclude all non-RCTs, such as review, non-clinical trials, and uncontrolled trials.

Information sources: We will search electronic databases in Cochrane Library, PUBMED, EMBASE, Web of Science, CINAHL, and China National Knowledge Infrastructure from inception to the present. These databases will be searched for eligible RCTs published without restrictions to the language and publication time. The detailed search strategy of Cochrane Library is provided. Similar search strategies will be modified for other electronic databases. In addition, we will retrieve other sources, such as conference abstracts, ongoing or unpublished studies from clinical trial registry, and reference lists of associated reviews.

Main outcome(s): The primary outcomes are total ovulation rate and total pregnancy rate. The secondary outcomes are levels of sex hormone (such as luteinizing hormone, follicle stimulating hormone, and androstadiendione), pregnancy loss, ectopic pregnancy, pregnancy and neonatal complications, and adverse events.

Data management: Two researchers will independently extract data from eligible trials using pre-piloted standardized database structured form, and any conflict will be cleared up by a third researcher through discussion. We will extract data of title, first author, country, type of PCOS, number of arms, number of patients, trial setting, trial design, trial methods, details of CCBCD and comparators, outcomes and their measurement time points, results, findings, withdrawals, and adverse events. Any disagreement will be resolved by a third researcher. We will contact primary trial authors to request any insufficient, unclear or missing data. If we can not obtain such data, we will perform outcome data analysis using intention-to-treat analysis.

Quality assessment / Risk of bias analysis: The methodological study quality of all included RCTs will be assessed using Cochrane risk of bias tool. It has seven domains, and each one is further rated as 'high', 'unclear' or 'low' risk of bias. If there are divergences between two researchers, we will invite a third researcher to solve those dissimilarities through discussion.

Strategy of data synthesis: RevMan 5.3 software will be utilized for data analysis. The effect size of continuous data will be estimated using standardized mean difference (MD) and 95% confidence intervals (CIs), and that of dichotomous data will be expressed using risk ratio and 95% CIs. We will apply I^2 statistic to employ statistical heterogeneity. $I^2 \leq 50\%$ suggests little heterogeneity, and we will pool outcome data using a fixed-effects model, and will carry out a meta-analysis if sufficient data are extracted from included trials. $I^2 > 50\%$ exerts remarkable heterogeneity, and we will undertake subgroup analysis and meta-regression to explore possible sources of obvious heterogeneity.

Subgroup analysis: A subgroup analysis will be performed according to the different study information, patient characteristics, study quality, sample size, and outcome indicators.

Sensibility analysis: **A sensitivity analysis will be conducted to test the robustness of study findings by eliminating low quality studies.**

Country(ies) involved: **China.**

Keywords: **Polycystic ovary syndrome; clomifene citrate; Bushen Culuan Decoction; efficacy; safety.**

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