INPLASY PROTOCOL

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

Conflicts of interest:
None declared.

Effectiveness and safety of electroacupuncture for Diminished Ovarian Reserve: a protocol for an overview of systematic reviews and meta-analysis

Ping, YL[1]; Zou, KX[2]; Feng, XL[3].

Review question / Objective: **This study aims at evaluating the curative effect and safety of EA treatment for DOR through systematic review and meta-analysis.**
Condition being studied: **Diminished Ovarian Reserve (DOR) refers to a decreased number and/or quality of oocytes, accompanied by changes in Anti-Mullerian Hormone (AMH), Follicle-Stimulating Hormone (FSH) and Antral Follicle Counting (AFC). In China, electroacupuncture (EA) is widely used as an alternative treatment for DOR. Several randomized controlled trials (RCTs) have reported that electroacupuncture is effective in treating DOR patients. The evidence, however, has not been systematically integrated. Therefore, this study aims at evaluating the curative effect and safety of EA treatment for DOR through systematic review and meta-analysis.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 December 2022 and was last updated on 11 December 2022 (registration number INPLASY2022120045).

INTRODUCTION

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METHODS

Participant or population: It will include women diagnosed with DOR. DOR study participants of all ages can be included regardless of race, occupation, education, national origin, etiology, and severity.

Intervention: One treatment intervention used in the trial group will include EA with unlimited duration, duration and frequency of treatment.

Comparator: The control group may be a blank control group, a placebo group, a drug treatment group, a psychological control group, or another active treatment group. If the combination therapy has the same 2 groups, the case involving EA and other combinations of therapies.

Study designs to be included: Only randomized controlled trials (RCTS) published in English and Chinese for EA in patients with DOR were included, and publication dates were not restricted.

Eligibility criteria: Published clinical studies which were reported in Chinese or English, and meet the "PICOS", will be considered for inclusion in this overview.

Information sources: We will search three foreign electronic databases (Cochrane Library, Embase, Pubmed) and four Chinese electronic databases (Wanfang Database, CNKI Database, Weipu Chinese Science and Technology Journal Database, and China Biomedical Literature Database) from the database establishment to December 2022.

Main outcome(s): The mean change from baseline in the AFC at week 12 and serum FSH, LH, E2, and AMH levels.

Additional outcome(s): 1. Endometrial thickness and ovarian arterial blood flow indicators. 2. The length of Menstrual cycle. 3. Adverse reactions, such as dizziness, nausea and vomiting, severe swelling and pain at the acupuncture site, etc. 4. Kupperman Rating Scale or other relevant symptom assessment scale.

Data management: Two researchers will independently select research documents and extract information according to inclusion and exclusion criteria. Firstly, the literature with repeated retrieval is removed, and then the title and abstract are scanned for preliminary screening. Second, we will download the full text of the relevant study to review the details. If there is any disagreement, the two researchers will discuss it and come to an agreement. If no consensus is reached, a third researcher makes the final decision. Details of the selection process are displayed in the flowchart. The extracted literature information mainly included study characteristics (author, year of publication, region, sample size, follow-up time), patient characteristics, treatment methods, and study results (primary outcome and secondary outcome indicators).

Quality assessment / Risk of bias analysis: The Cochrane bias risk assessment tool will be used to evaluate the risk of bias from six aspects: selection bias, implementation bias, measurement bias, follow-up bias, reporting bias, and additional biases. Two independent researchers will evaluate the risk of bias. The evaluation criteria can be divided into 7 items, and for each item, low bias, uncertain risk of bias and extreme bias will be used to judge and classify the research quality. A third reviewer should be consulted if the assessment of bias is controversial. RevMan V.5.3.5 will be used to create the sample diagram.

Strategy of data synthesis: Stata12.0 software will be used. A hazard ratio with a

95% confidence interval (CI) will be used to evaluate efficacy. Among them, odds ratio (OR) and relative risk (RR) are commonly used for binary outcome data. Where analytical continuity variables are involved, the weighted mean difference (WMD) or standard mean difference (SMD) will be analyzed. If there is any data missing in the research results, we will actively contact the corresponding author to supplement the content. If the corresponding author cannot be reached, the data will be processed separately. The heterogeneity test will be conducted for the included studies. If the results of each study had low heterogeneity (I2≤50%), the fixed effects model was used for analysis; otherwise, the random effects model will be used for analysis. Odds ratio (OR) and 95% confidence interval (95%CI) will be used as statistical indicators. P<0.05 will be considered statistically significant. As for the value of I2, 25-50% is mild heterogeneity, 50%-75% is moderate heterogeneity, and 75%-100% is elevated heterogeneity.

Subgroup analysis: If necessary, subgroup analyses will be performed to assess sources of heterogeneity. For example, different regions, intervention forms, follow-up time and other factors will be analyzed.

Sensitivity analysis: To assess the robustness of the results, a sensitivity analysis will be performed by removing low-quality articles.

Language restriction: The language of publication is limited to Chinese or English.

Country(ies) involved: China.

Other relevant information: None.

Keywords: electroacupuncture, Diminished Ovarian Reserve, overview, protocol.

Contributions of each author:
Author 1 - Yunlu Ping.
Author 2 - Kangxi Zou.
Author 3 - Xiaoling Feng.

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