INPLASY

Traditional Chinese medicine auxiliary to IVF-ET for women with diminished ovarian reserve: A protocol of systematic review and meta-analysis

INPLASY202370098

doi: 10.37766/inplasy2023.7.0098

Received: 24 July 2023

Published: 24 July 2023

Zhu, C; Tao, YJ; Liu, SY; Yang, CF.

Corresponding author:
Can Zhu

zhucan9105@foxmail.com

Author Affiliation:
Guizhou University of Traditional Chinese Medicine; Chengdu University of Traditional Chinese Medicine.

ADMINISTRATIVE INFORMATION

Support - The National Natural Science Foundation of China (grant no. 82360952).

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

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202370098

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 July 2023 and was last updated on 26 June 2024.

INTRODUCTION

Review question / Objective To evaluate the effects of traditional Chinese medicine (TCM) as an adjuvant therapy to in vitro fertilization-embryo transfer (IVF-ET) for women with diminished ovarian reserve (DOR).

Condition being studied DOR often leads to low fertility and poses a great challenge to IVF-ET. TCM is commonly undertaken during IVF-ET in DOR patients, although its role is still controversial. However, the systematic review and meta-analysis on TCM for DOR patients receiving IVF-ET has not previously been reported. Therefore, it is necessary to perform the study.

METHODS

Participant or population DOR patients undergoing IVF-ET.

Intervention TCM auxiliary to IVF-ET, including all types of TCM.

Comparator IVF-ET, or placebo treatment auxiliary to IVF-ET.

Study designs to be included Only randomized controlled trials (RCTs) will be included. Crossover randomized controlled trials that do not provide pre-crossover data will be excluded.

Eligibility criteria We will only include RCTs that compare TCM with placebo treatment or no adjuvant treatment during IVF-ET for DOR patients. And the type of TCM treatment includes herb prescription, acupuncture, acupuncture combined with medication, and so on.

Information sources We search for RCTs in the following electronic databases, including Cochrane Library, PubMed, Embase, and the Chinese Biomedical database (SinoMed), Chinese National Knowledge Infrastructure (CNKI), and Chinese Technology Periodical Database (VIP), from inception to June 14, 2024. We also search for previous systematic reviews on TCM for DOR

patients receiving IVF-ET. Additionally, the following databases of ongoing trials are retrieved: Clinicaltrials.gov, the World Health Organization's International Clinical Trials Registry Platform, and Chinese Clinical Trial Register.

Main outcome(s) Clinical pregnancy rate (CPR), defined as the presence of at least one gestational sac with fetal heartbeat, which was confirmed by ultrasound 5 weeks after transfer.

Additional outcome(s) High-quality embryo rate (HER); oocytes retrieved (OR); antral follicle count (AFC); anti-Müllerian hormone (AMH); basal follicle stimulating hormone (bFSH).

Quality assessment / Risk of bias analysis The Cochrane risk of bias assessment tool is used to assess the following factors: random method, allocation concealment, blinding, incomplete outcome data, selective reporting and other bias. Two researchers conduct independent evaluations, with any disagreements discussed and resolved with the third researcher.

Strategy of data synthesis The data will be pooled for meta-analysis with Review Manager 5.4 software. The outcome measures are expressed with risk ratio (RR) when acted as dichotomous data, or mean difference (MD) when performed as continuous data, and a 95% confidence interval (CI). And the statistical heterogeneity between included studies is evaluated by using both the I2 statistic and the P-value of the x2 test. The following guide interpreting I2 values is suggested by Cochrane Handbook: 0-40% might not be important; 30-60% may represent moderate heterogeneity; 50-90% may represent substantial heterogeneity; and 75-100% may represent considerable heterogeneity. Whether a fixed-effects model or a random-effects model is applied depends on the comprehensive analyses of statistical, clinical and methodological heterogeneity. For our meta-analysis, because the clinical heterogeneity of TCM protocols in included studies is expected, we will use the random-effects model and investigate the sources of heterogeneity through subgroup or sensibility analyses for the primary outcome. When at least ten trials are included, we will construct funnel plots to assess the likelihood of publication bias.

Subgroup analysis (1) Type of TCM: Herb prescription, acupuncture, or acupuncture combined with herb. (2) Type of control: Placebo treatment, or no adjuvant treatment. (3) Menstrual cycles of treatment: One, two, three, or four.

Sensitivity analysis Excluding the trials which are potential contributors to heterogeneity, the meta-analysis will be performed again.

Language restriction With no restriction.

Country(ies) involved Mainland China.

Keywords Traditional Chinese medicine (TCM); In vitro fertilization-embryo transfer (IVF-ET); Diminished ovarian reserve (DOR); Infertility.

Contributions of each author
Author 1 - Can Zhu.
Author 2 - Yujing Tao.
Author 3 - Shanyu Liu.
Author 4 - CF Yang.