INPLASY PROTOCOL

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Review question / Objective: The purpose of this paper is to evaluate the efficacy and safety of different complementary and alternative therapies for tubal obstructive infertility.

Condition being studied: Infertility will become the third largest disease in the 21st century predicted by the WHO, only after cancer and cardiovascular and cerebrovascular diseases. Infertility is directly related to personal physical and mental health, family stability, and even affects the sustainable development of society. Fallopian Tubal obstruction is one of the important causes of female infertility. The incidence of tubal obstruction was approximately 19% in women with primary infertility and approximately 29% in women with secondary infertility. With the development of ART, IVF-ET has made great progress in the treatment of tubal obstructive infertility. At the same time , it also brings many complications such as multiple pregnancy, premature birth, birth defects, OHSS, high cost and ethical challenges. Traditional Chinese medicine has a long history in treating tubal obstructive infertility and complementary and alternative therapies are effective and can improve pregnancy rate. Many studies and system reviews have confirmed the clinical effect of complementary and alternative therapies for infertility.Complementary and alternative therapies that are widely used to treat tubal tubal blockage include acupressure, retention of enema with Chinese medicine, moxibustion, et al.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 January 2021 and was last updated on 20 January 2021 (registration number INPLASY202110076).

INTRODUCTION

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METHODS

Participant or population: Married women of childbearing age diagnosed with tubal obstructive infertility.

Intervention: Complementary and alternative therapies in combination with or without other treatments.

Comparator: Comparing complementary and alternative therapies including acupressure, retention of enema with Chinese medicine, moxibustion, et al.

Study designs to be included: We will include only randomized controlled trials (RCTs).

Eligibility criteria: Married women of childbearing age diagnosed with tubal obstructive infertility will be included.

Information sources: PubMed, Cochrane Library, EMBASE, Web of Science, Chinese Biomedical Literature Database (SinoMed), Chinese National Knowledge Infrastructure (CNKI), Wanfang database and VIP database.

Main outcome(s): (1) Clinical total effective rate. (2) Clinical pregnancy rate: Clinical pregnancy is diagnosed on the basis of absence of menstruation and ultrasound. (3) Tubal recanalization rate.

Additional outcome(s): (1) Adverse reactions. (2) Quality of life. (3) Depression, anxiety or stress symptoms.

Quality assessment / Risk of bias analysis: According to Cochrane risk assessment tool, we will evaluate risk of bias in seven domains of each eligible trial.

Strategy of data synthesis: 1. Pairwise meta-analyses. In the process, continuous data will be described by Mean Difference (MD) or Standardized Mean Difference (SMD). Odds Ratio (OR) will be used for dichotomous data. The 95% credible interval (CI) will be calculated. 2. Network meta-analyses. We will conduct NMAs to examine the comparative efficacy and safety of complementary and alternative therapies. Random-effects model will be used to compare the direct and indirect evidence. WinBUGS and Stata software will be employed to perform network metaanalysis.

Subgroup analysis: If there is enough evidence, we will conduct subgroup analysis to explore the sources of heterogeneity.

Sensibility analysis: We will perform sensitivity analysis for the primary outcomes by excluding studies with high risk of bias.

Country(ies) involved: China.

Keywords: complementary and alternative therapies, tubal obstructive infertility, network meta-analysis, protocol.

Contributions of each author:

Author 1 - Shuang-Qian Dong. Author 2 - Xing-Long Zhao. Author 3 - Ying Sun. Author 4 - Jian-Wei Zhang.