INPLASY PROTOCOL

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None declared.

Conventional surgery Combined with traditional Chinese medicinal retentionenema for tubal obstructive infertility: A protocol of Systematic Review and Meta-Analysis

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Review question / Objective: **The purpose of this paper is to evaluate the efficacy and safety of conventional surgery combined with traditional Chinese medicinal retention enema for tubal obstructive infertility.**
Condition being studied: **Salpingitis is a major cause of infertility. Clinical studies about conventional surgery combined with Chinese medicinal retention enema for tubal obstructive infertility are increasing, while systematic reviews about its efficiency remain inexistent.So we will organize, analyze, summarize studies that we could find on all databases about Conventional surgery Combined with traditional Chinese medicinal retention enema for tubal obstructive infertility to provide a clear and significant evidence for clinicians.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 March 2022 and was last updated on 08 March 2022 (registration number INPLASY202230033).

INTRODUCTION

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we could find on all databases about Conventional surgery Combined with traditional Chinese medicinal retention enema for tubal obstructive infertility to provide a clear and significant evidence for clinicians.

METHODS

Participant or population: All participants who have been diagnosed with fallopian tubal occlusion of female infertility will be included. There are no restrictions on age, region, nation, belief, ethnicity, sources, and courses of disease. Acute and subacute inflammatory reaction of genitals, luteal phase defect, serious cardiovascular and cerebrovascular diseases, congenital or acquired defects will be not included.

Intervention: All patients enrolled in the study received conventional operation for tubal obstructive infertility, including hydrotubation, Gynecological endoscopic operating, and interventional recanalization. On this basis, the intervention group was given conventional operation with traditional Chinese medicine retention enema.

Comparator: The control group just applied for conventional operation for tubal obstructive infertility.

Study designs to be included: We will include only randomized controlled trials published in both Chinese and English. However, animal experiments, reviews, case reports, and non-randomized controlled trials are excluded.

Eligibility criteria: 1. Types of studies. We will include only randomized controlled trials published in both Chinese and English. However, animal experiments, reviews, case reports, and non-randomized controlled trials are excluded. 2. Types of participants. All participants who have been diagnosed with fallopian tubal occlusion of female infertility will be included. There are no restrictions on age, region, nation, belief, ethnicity, sources, and courses of disease. Acute and subacute inflammatory reaction of genitals, luteal phase defect,serious cardiovascular and cerebrovascular diseases,congenital or acquired defects will be not included. 3. Types of interventions. There is no requirement for the intervention course, the specific contents of the control group and the experimental group are as follows. 3.1. Control intervention. The control group just applied for conventional operation for tubal obstructive infertility. 3.2. Experimental interventional. All patients enrolled in the study received conventional operation for tubal obstructive infertility,including hydrotubation, Gynecological endoscopic operating, and interventional recanalization. On this basis, the intervention group was given conventional operation with traditional Chinese medicine retention enema.

Information sources: We conducted a systematic search for relevant documents in the Chinese and English databases, and the search time is limited to February 14, 2022. The following eight databases are included: PubMed, EMBASE, Web of Science, The Cochrane Library, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP), Wanfang Database.We adopt the combination of heading terms and free words as search strategy which decided by all the reviewers. Relevant journals were searched to trace the references included in the study. Other resources will be searched if necessary.

Main outcome(s): (1) Clinical pregnancy rate: Clinical pregnancy is diagnosed on the basis of absence of menstruation and ultrasound. (2)Tubal recanalization rate. (3)The rate of adverse events: such as incidence of ectopic pregnancy. (4) Efficacy of TCM syndrome.

Quality assessment / Risk of bias analysis: Two researchers will evaluate the quality of RCTs by using the risk assessment tool recommended in Cochrane Handbook 5.3. This evaluation includes 6 factors: generation of random sequences, blinding

of investigators and participants, blinding of study results, completeness of outcome data, selectivity in reporting of results, and other biases. If there are missing or unclear data, we will attempt to contact the original authors by email. If no reply is received or the authors have not saved the original data, we will analyze only the data that are useful in the literature or analyze the missing data in the discussion.

Strategy of data synthesis: This study involves bicategorical and continuous variables. The relative risk (RR) is used as an effect measure in the bicategorical variables and the mean differences (MD) in the continuous variables, and the software is able to obtain the point estimates and the 95% confidence interval (CI) for the 2. I2 is an important index for making the heterogeneity judgment. If I2<50%, a fixed effects model is used; if I2≥50%, a random effects model is used. For each combined analysis, the test of heterogeneity is measured using the cardinality statistic.

Subgroup analysis: Subgroup analysis: If P50%, there is significant heterogeneity between studies, a random effect model will be adopted. Further analysis of the source of heterogeneity, if necessary, perform subgroup analysis. There are clinical and methodological differences in the experimental studies. Therefore, random effects models will be selected in this study. Finally, a funnel chart will be drawn to evaluate the publication bias of the literature.

Sensitivity analysis: If heterogeneity is present, we will analyze the cause through sensitivity analysis.

Country(ies) involved: China.

Keywords: Chinese medicinal retention enema,meta-analysis, protocol, systematic review.

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