

INPLASY PROTOCOL

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Corresponding author:
Jiahua Peng

845878196@qq.com

Author Affiliation:
Institute of Obstetrics and Gynecology of Traditional Chinese Medicine, Jiangxi University of Traditional Chinese Medicine.

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None declared.

Effect assessment of laparoscopy in combination with traditional Chinese medicine decoction in the treatment of endometriosis: A protocol for systematic review and meta-analysis

Peng, J¹; Wang, R²; Ding, Z³; Song, X⁴.

Review question / Objective: In recent years, laparoscopy has gradually replaced open surgery with its advantages of minimal invasiveness, fewer complications, and fast healing, but surgical treatment alone still cannot solve the problem. EMs are called "pelvic sandstorms", both radical and conservative operations can only achieve the goal of reducing the removal of visible lesions and restoring normal anatomical structures as much as possible. The recurrence rate of postoperative pain or endometriosis of the ovary remains high. In traditional Chinese medicine, the corresponding disease names are "dysmenorrhea", "zhengren", "infertility" and so on. There are a large number of domestic literatures that Chinese medicine can effectively treat EMs. The treatment of endometriosis with traditional Chinese medicine plays an effective clinical role in alleviating the pain of the disease, slowing the progression of the disease, and preventing the recurrence of the disease after the operation, and has clinical advantages.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 June 2021 and was last updated on 21 June 2021 (registration number INPLASY202160074).

INTRODUCTION

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anatomical structures as much as possible. The recurrence rate of postoperative pain or endometriosis of the ovary remains high. In traditional Chinese medicine, the corresponding disease names are "dysmenorrhea", "zhengren", "infertility" and so on. There are a large number of domestic literatures that Chinese medicine can effectively treat EMs. The treatment of endometriosis with traditional Chinese medicine plays an effective clinical role in alleviating the pain of the disease, slowing the progression of the disease, and preventing the recurrence of the disease after the operation, and has clinical advantages.

Condition being studied: Modern studies have shown that integrated traditional Chinese and western medicine has a good clinical effect in the treatment of EMs. However, the existing domestic and foreign literatures on the treatment of EMs with integrated traditional Chinese and western medicine are numerous and messy, lacking of systematic reviews and meta analysis results in insufficient clinical evidence for the treatment of dysmenorrhea by laparoscopy and traditional Chinese medicine. Through systematic evaluation of the clinical efficacy of laparoscopy combined with traditional Chinese medicine in the treatment of EMs, to guide Chinese and Western doctors in the rational treatment of EMs and relieve the pain of dysmenorrhea patients. In order to obtain conclusive evidence of the efficacy of laparoscopy combined with traditional Chinese medicine in the treatment of EMs, this study uses evidence-based medicine to find clinical randomized controlled trials (RCTs) studies of silver application in the treatment of diabetic feet, so as to provide clinicians with evidence-based evidence of.

METHODS

Participant or population: Patients diagnosed with EMs, the diagnosis meets the guidelines of the American Society of Reproductive Medicine (ASRM)⁷ diagnostic criteria for endometriosis. There will also be no restrictions based on gender, race, and the course of the disease. However,

the EMs combined with pelvic infections, endometrial polyps, intrauterine adhesions, cervical stenosis, uterine malformations and other diseases will be excluded.

Intervention: The experimental group was laparoscopic surgery combined with Chinese medicine decoction.

Comparator: The control group was simply laparoscopic surgery.

Study designs to be included: The type of literature research is RCTs.

Eligibility criteria: We will include all randomized controlled trials (RCTs) investigating laparoscopic surgery combined with Chinese herbal decoction in the treatment of EMs. It will be excluded if the following situations are included. 1.The outcome indicators in the literature are not clear or the outcome indicators cannot be extracted. 2.For research and reports with repeated substantive content from the same unit or the same time period and signed by the same author, select one of them as the target document. 3.Interventions incompatible with the inclusion criteria and animal experiments.

Information sources: A systematic literature search will be conducted at China National Knowledge Infrastructure (CNKI), WanFang databases, VIP, SinoMed, Pubmed, Embase, Web of Science, and the Cochrane library. The search period limit is from the time the date of database establishment to June 21, 2021. To ensure the comprehensiveness of the search, relevant references and conference literature are also included. The search will identify all randomized controlled trials to evaluate the effectiveness and safety of laparoscopy combined with Chinese herbal decoction in the treatment of EMs. Afterwards, the Boolean operators "OR" and "AND" will be used to combine the following search terms: "EMs", "Endometriosis", "Chinese medicine decoction", "traditional Chinese medicine", "TCM", "randomized controlled trial", "RCT".

Main outcome(s): The primary outcome indicators include serum follicle stimulating hormone (FSH), luteinizing hormone (LH), estradiol (E2), pregnancy rate, recurrence rate.

Additional outcome(s): Antral follicles count (AFC), ovarian volume and adverse reactions.

Quality assessment / Risk of bias analysis: The risk of bias in the final included studies will be evaluated based on the guidelines of the Cochrane Handbook for Systematic Reviews of Interventions. The evaluation criteria include 7 items: selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias. Each item will be graded into three levels: "high risk", "low risk", and "not clear". This work will also be done independently by 2 reviewers.

Strategy of data synthesis: Revman 5.3 was used to perform statistical analysis on the extracted data and draw forest maps. Choose appropriate statistics and statistical methods according to the type of data. For binary data, calculate its odds ratio (OR) and its 95% CI. For measurement data, calculate the weighted mean difference (WMD) and 95% CI.

Subgroup analysis: Subgroup analysis can be conducted according to the different sources of heterogeneity, such as the following aspects: treatment duration, disease course, underlying disease, race, gender, age, etc. If no clear source of heterogeneity can be found, only descriptive analysis can be conducted.

Sensitivity analysis: If the heterogeneity between the research results is large ($P \leq 0.1$, $I^2 \geq 50\%$), sensitivity analysis should be used to explore the source of the heterogeneity. The main methods of sensitivity analysis are: 1. Change the analysis model, when the heterogeneity is high, use the random effects model. 2. Documents are excluded one by one. If the heterogeneity does not change after being eliminated separately, the result is relatively robust. If the heterogeneity of a certain

document is eliminated, then this article may be the source of the heterogeneity. 3. According to the different characteristics of the literature, such as region, dose, etc., conduct subgroup analysis.

Country(ies) involved: China.

Keywords: Laparoscopy; Traditional Chinese Medicine; Endometriosis; Meta analysis.

Contributions of each author:

Author 1 - Jiahua Peng.

Author 2 - Ruiqi Wang.

Author 3 - Zhiling Ding.

Author 4 - Xin Song.