INPLASY PROTOCOL

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None declared.

Network meta-analysis of 7 kinds of Chinese patent medicine combined with mifepristone in the treatment of uterine fibroids

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Review question / Objective: **To compare the clinical efficacy of 7 different Chinese patent medicine combined with mifepristone and mifepristone alone in the treatment of uterine fibroids.The selected method is clinical randomized controlled trials.**
Condition being studied: **Uterine fibroids are benign. They belong to the category of "abdominal mass" in traditional Chinese medicine, and pathogenesis is mainly caused by weakness of the body, qi stagnation, and blood stasis. Drug therapy is the preferred treatment of uterine fibroids in clinical practice, and mifepristone is the most commonly used drug. In the past decade, a large number of clinical randomized controlled trials have proven that Chinese patent medicine combined with mifepristone in the treatment of uterine fibroids has a better curative effect, fewer adverse reactions, and higher safety than mifepristone alone. However, there is a lack of evidence-based research. This study aims to integrate clinical data through network meta-analysis to provide more evidence-based medical evidence for clinical medication.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 May 2022 and was last updated on 16 May 2022 (registration number INPLASY202250101).

INTRODUCTION

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drug. In the past decade, a large number of clinical randomized controlled trials have proven that Chinese patent medicine combined with mifepristone in the treatment of uterine fibroids has a better curative effect, fewer adverse reactions, and higher safety than mifepristone alone. However, there is a lack of evidence-based research. This study aims to integrate clinical data through network meta-analysis to provide more evidence-based medical evidence for clinical medication.

METHODS

Participant or population: The patients were all clinically diagnosed with uterine fibroids. The age, sex, race, and region of the patients were not limited. The diagnostic criteria used for uterine fibroids complied with "Obstetrics and Gynecology", "Practice of Obstetrics and Gynecology", "Chinese expert consensus on the diagnosis and treatment of uterine fibroids", "Gynecology of Traditional Chinese Medicine", and "Guidance Principle of Clinical Study on New Drug of Traditional Herbal Medicine".

Intervention: The treatment group was treated with 1 of the 7 Chinese patent medicines (Guizhi Fuling Wan/Capsule, Gongliuxiao Capsule, Gongliuqing Capsule, Danbie Capsule, Gongliuning Capsule, Hongjinxiaojie Caspsule and Xiaojiean Capsule) combined with mifepristone.

Comparator: The control group was treated with mifepristone alone.

Study designs to be included: We included only published clinical RCTs in English and Chinese.

Eligibility criteria: Exclusion criteria. Other diseases; repeated published study; incomplete or wrong data; no clear diagnostic criteria; no clear criteria for efficacy evaluation; no clear dosage or dosage form; and no definite course of treatment.

Information sources: The literature search will be conducted in three English databases (Medline, Embase and Cochrane Library) and four Chinese databases (China National Knowledge Infrastructure, Chongqing VIP information, WanFang and SinoMed).

Main outcome(s): Total effective rates, total effective rates=(total cases – invalid cases)/ total cases 100%; Uterine fibroid volume.

Additional outcome(s): Hormone index, including progesterone, oestradiol, follicle-stimulating hormone, and luteinizing hormone; and adverse reaction.

Quality assessment / Risk of bias analysis: Risk of bias was assessed by 2 researchers using the Cochrane risk of bias tool recommended by the Cochrane reviewer's handbook. According to the evaluation content of the manual, each included study was evaluated from random methods, allocation concealment, blinding, completeness of outcome data, selective reporting results, and other sources of bias. Each project was divided into 3 types of results: high risk, low risk, and uncertainty risk.

Strategy of data synthesis: RevMan 5.3 (Cochrane UK, Summertown Pavilion, 18 - 24 Middle Way, Oxford, UK) was used to evaluate the quality of the literature data, and R language (Oakland University, New Zealand) was used to analyze treatment measures. A forest map and probability ranking map of various interventions were drawn. The network evidence map and correction comparison funnel map of various interventions were drawn with STATA 14.0 software (Lakeway Drive, College Station, Texas, USA). The R language program netmeta was used through relevant instructions with the Bayesian Markov Chain Monte Carlo algorithm for random effect model data results to achieve network data analysis and mapping. The odds ratio and its 95% confidence interval were used to represent the effect amount in the enumeration data. The measurement data used the mean ifference and its 95% confidence interval to represent the effect. When the data were incomplete, the

author was ontacted; if we were unable to obtain complete data, the article was excluded. The ranking probability diagram was used to rank the efficacy of interventions, with α=0.05 as the test level.

Subgroup analysis: There was no subgroup plan.

Sensitivity analysis: If significant heterogeneity was detected and data were sufficient, we used subgroup analysis to determine the reasons for the heterogeneity and compare the effects of each group.

Country(ies) involved: China.

Keywords: Chinese patent medicine, mifepristone, uterine fibroids, network meta-analysis, protocol.

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