INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy and safety of Guizhi Fuling Decoction combined with Mifepristone in the treatment of Uterine fibroids A protocol for systematic review and meta-analysis

Wang, X[1]; Zhang, L[2]; Ma, M[3].

Review question / Objective: **P: All participants were diagnosed with uterine fibroids and had no age or race restrictions. I: The intervention group was Guizhiporing decoction combined with mifepristone. C: The control group was treated with mifepristone alone. O: The primary outcomes included the effective rate, uterine leiomyoma volume (ULV, cm3), uterine volume (UV, cm3), estradiol (E2), luteinizing hormone (LH), follicle-stimulating hormone (FSH), and progesterone (P) levels. The secondary outcomes included the total incidence of adverse events (including nausea, vomiting, loss of appetite, etc.) (%).**
Condition being studied: **Uterine fibroids. We will search the databases of Pubmed, Cochrane Library, Web of Science , EMBASE, Chinese Biomedical Literature Database (CBM), China National Knowledge infrastructure (CNKI), Chinese Scientific Journal Database(VIP),and Wanfang database from the date of establishment to May, 2021. EndNote X8 and RevMan5.2 will be used for study selection, data analysis and management. The study selection, data extraction and quality assessment will be conducted independently by two researchers. In case of disagreement, a third party should be sought for assistance.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 May 2021 and was last updated on 16 May 2021 (registration number INPLASY202150061).

INTRODUCTION

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METHODS

Participant or population: All participants were diagnosed with uterine fibroids and had no age or race restrictions.

Intervention: Guizhiporing decoction combined with mifepristone.

Comparator: Treated with mifepristone alone.

Study designs to be included: All the randomized controlled trials (RCTs).

Eligibility criteria: The study will include all participants were diagnosed with uterine fibroids and had no age or race restrictions.

Information sources: We'll retrieve 8 databases, the electronic databases, including the PubMed, Embase, Cochrane Library, Web Of Science, Chinese Biomedical Literature Database (CBM), China National Knowledge Infrastructure (CNKI), Wanfang Database (WF), China Science Journal Database (VIP), The retrieval date was established from the database to May 2021, without any language restriction.

Main outcome(s): The primary outcomes included the effective rate, uterine leiomyoma volume (ULV, cm3), uterine volume (UV, cm3), estradiol (E2), luteinizing hormone (LH), follicle-stimulating hormone (FSH), and progesterone (P) levels.

Quality assessment / Risk of bias analysis: Two independent authors will evaluate the bias risk in each included study using Cochrane Collaboration's "Risk of bias" assessment tool[2]. Any disagreement will be resolved via consultation with a third author. The main items to be considered are as follows: 1) randomization plan; 2) group concealment; 3) blinding method; 4) incomplete data reporting; 5) selective outcome report; and 6) other sources of bias. Each item will be evaluated as "high," "low," or "unclear."

Strategy of data synthesis: And will searching the relevant literature by combining subject words with free words, search terms consist ("Uterine leiomyoma" or "Uterine fibroids" or "Fibroma, Uterine" or "Fibroid , Uterine" or "Leiomyoma , Uterine" or "Tumors, Fibroid" or "Fibroid Uterus") AND ("Guizhi Fuling Decoction" or "Guizhi Fuling").

Subgroup analysis: None.

Sensitivity analysis: Through the study of large weight of elimination effect, the sensitivity analysis was performed to test the stability of the results of meta-analysis.

Country(ies) involved: China.

Keywords: meta-analysis, randomized controlled trial, uterine fibroids, guizhi fuling decoction.

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