INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Effects of different dosages of mifepristone on uterine leiomyoma in premenopausal women: a meta-analysis of randomized controlled trials

Huang, JX[1]; Lin, X[2]; Zhang, YW[3].

Review question / Objective: **The aim of this meta-analysis of randomized controlled trials is to compare the efficacy and safety of different dosages of mifepristone for premenopausal women with uterine leiomyoma.**
Condition being studied: **Uterine leiomyoma is the most common benign tumor in female reproductive system. Recent studies have shown that women aged 45 years and over have a lifetime leiomyoma risk of more than 60%. Excessive menstruation, abnormal uterine bleeding, pelvic pain or pressure, infertility and repeated pregnancy loss are usually associated with leiomyoma. Although surgery and radiotherapy are often used to treat these tumors, drug therapy including gonadotropin releasing hormone agonists and progesterone modulators is the first-line treatment for leiomyoma. Recent studies have shown that progesterone is essential for the maintenance and growth of uterine leiomyoma. Mifepristone is an anti-progesterone drug, which has been proved to be effective in the treatment of uterine leiomyoma, resulting in a decrease in the size and symptoms of leiomyoma. The effect of mifepristone varies with the time or dose of teatment.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 November 2022 and was last updated on 05 November 2022 (registration number INPLASY2022110020).

INTRODUCTION

Review question / Objective: **The aim of this meta-analysis of randomized controlled trials is to compare the efficacy and safety of different dosages of mifepristone for premenopausal women with uterine leiomyoma .**

Condition being studied: **Uterine leiomyoma is the most common benign tumor in female reproductive system.**

Recent studies have shown that women aged 45 years and over have a lifetime leiomyoma risk of more than 60%. Excessive menstruation, abnormal uterine bleeding, pelvic pain or pressure, infertility and repeated pregnancy loss are usually associated with leiomyoma. Although surgery and radiotherapy are often used to treat these tumors, drug therapy including gonadotropin releasing hormone agonists and progesterone modulators is the first-line treatment for leiomyoma. Recent studies have shown that progesterone is essential for the maintenance and growth of uterine leiomyoma. Mifepristone is an anti-progesterone drug, which has been proved to be effective in the treatment of uterine leiomyoma, resulting in a decrease in the size and symptoms of leiomyoma. The effect of mifepristone varies with the time or dose of treatment.

METHODS

Participant or population: Premenopausal women with uterine leiomyoma treated by mifepristone.

Intervention: Mifepristone was the main intervention.

Comparator: Placebo or Gonadotropin-releasing hormone analog like Enantone or different doses of mifepristone.

Study designs to be included: Randomized controlled trials (RCTs) will be included.

Eligibility criteria: Inclusion criteria:1.Patients measured leiomyoma related symptoms before and after treatment;2.Patients measured uterine or leiomyoma volume before and after treatment.The exclusion criteria: 1.submucosal fibroids; 2.suspicion or diagnosis of uterine or endometrial malignancy; 3.adnexal mass or endometriosis; 4.coagulation dysfunction and bleeding tendencies; 5.hepatic or renal malfunction;6.mifepristone therapy in the last 3 months.

Information sources: We will search the following databases for relevant English and Chinese literature: PubMed, Embase, Web of Science, Cochrane Library, Open Grey, Clinicaltrials.gov, Chinese Clinical Trial Registry, WANFANG, VIP Chinese Science and Technology Journal Database,CNKI, Chinese biomedical document service system(SinoMed).

Main outcome(s): Changes in uterine or leiomyoma volume.

Additional outcome(s): Leiomyoma-related symptoms, changes in endometrial thickness.

Quality assessment / Risk of bias analysis: Two researchers independently assessed the risk of bias in the included studies by using the Cochrane tool. Each study was classified as having high, low, or unclear risk according to the following seven items: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. A score of 1 to 3 was considered high risk, and a score of 4 to 7 was considered low risk. Any disagreement in the process was resolved by a third researcher.

Strategy of data synthesis: The meta-analysis was performed using Reviewer Manager 5.4. The 95% confidence intervals (CI) were used, mean differences (MD) were calculated for continuous variables. Data heterogeneity was assessed using the chi-square and I^2 tests. When heterogeneity was not significant ($P \geq .10$, $I^2 \leq 50\%$), a fixed-effects model was used for analysis; when heterogeneity was significant ($I^2 > 50\%$ or $P < .10$), a random-effects model was used.

Subgroup analysis: We will consider subgroups such as race ,the volume of uterine or leiomyoma at beginning of the trails.

Sensitivity analysis: We will use sensitivity analysis to test the stability and reliability of meta-analysis. It will be conducted by 2 methods: eliminating each study one by one; using random-effect model

(DerSimonian & Laird method) to test the results after using the fixed effectmode.

Country(ies) involved: **China (The First Clinical College, Guangzhou University of Chinese Medicine, Guangzhou, Guangdong Province, China).**

Keywords: **mifepristone; uterine leiomyoma; meta-analysis; randomized controlled trials.**

Contributions of each author:
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