INPLASY

Updating the efficacy and safety of different doses of mifepristone in the treatment of uterine fibroids: a meta-analysis

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 June 2024 and was last updated on 19 June 2024.

INTRODUCTION

Review question / Objective To provide a standard for the sensible administration of medications in clinical settings and to thoroughly assess the safety and effectiveness of mifepristone at dosages of 2.5 mg, 5 mg, 10 mg, 25 mg, and 50 mg in treating uterine fibroids. The study's findings included the patient's uterus volume or fibroids, menorrhagia and other symptoms related to uterine fibroids, and side effects like hot flashes.

Condition being studied Uterine myoma is the most common benign tumor of women, Uterine fibroids affect 70% of white women and >80% of African American women by the age of 50 years. From a histological perspective, fibroids are benign tumors of messy smooth muscle cells encased in a large extracellular matrix. Uterine fibroid tumors consume a significant amount of health care resources in the United States, the total direct cost to treat uterine fibroid tumors was estimated at 2,151,484,847 dollars. The enormous social and economic burden associated with uterine fibroids makes the development of a treatment strategy for these tumors imperative.

METHODS

Participant or population 1) symptomatic uterine leiomyomas,2) of reproductive age or premenopausal, 3) agreement to use a nonhormonal method of contraception, 4) agreement to keep a monthly log of all episodes of vaginal bleeding and adverse effects of mifepristone during treatment, 5) agreement to undergo ultrasound examinations in every follow-up or evaluation visit, and 6) agreement to undergo two endometrial biopsies.

Intervention Mifepristone in the treatment of uterine fibroids.

Comparator Placebo or Blank control.

Study designs to be included Randomized controlled trials or non-randomized controlled trials.

Eligibility criteria The preliminary study satisfied the following requirements: (1) under the diagnostic guidelines for uterine fibroids. (2)mifepristone of any concentration was used in at least 1 treatment arm(3) reporting of at least 1 outcome of interest, including the volume of the uterus or hysteromyoma, together with any associated symptoms or unfavorable reactions, etc. We exclude case report research, unclear or incomplete sources that ask for nothing, lack or have issues with data extraction, are inappropriate for group comparisons, or lack control subject research.

Information sources English databases(PubMed/ Medline, EMBASE, and the Cochrane library).

Main outcome(s)
(1) uterine/ fibroid volume
(2) symptoms of uterine fibroids: lower back pain, dyspareunia, pelvic pressure, bladder pressure, urinary symptoms, pelvic pain, pelvic pain score, rectal pain, mean menstrual blood loss, metrorrhagia, and hypermenorrhea.
(3) side effects: headaches, altered endometrial thickness, hot flashes, nausea, vomiting, diarrhea, decreased libido, and raised aspartate aminotransferase (ASAT) and aspartate alanine-transferase (ALAT) values.

Quality assessment / Risk of bias analysis Two independent researchers used the Cochrane Handbook 6.0 as a guide for their risk of bias assessment tool. The quality of the literature evaluation, the random method evaluation index, the dissemination of hidden information, the double-blind assessment of the participants and the perpetrators, the blind evaluation's outcome, the data's integrity, the results of selective reporting, and additional sources of bias were among them. There are seven initiatives, divided into three categories: low risk, high risk of bias, and unclear.

Strategy of data synthesis Utilizing RevMan5.4.1 software, a meta-analysis and Cochrane risk of bias map were created. The 95% confidence interval (CI) and mean differences (MD) are used for continuous variables, whereas odds ratios (OR) and 95% CI are used for binary classification variables. Fixed effect models are utilized in meta-analyses when heterogeneity (I 2) is less than 50%; in all other cases, random-effects models are employed.

Subgroup analysis Age and ethnicity may affect the effect of the intervention.

Sensitivity analysis Sensitivity analysis was carried out using the primary outcome indicator of the mifepristone and control groups—the uterine volume change.

Country(ies) involved China.

Keywords uterine fibroid; mifepristone; preoperative adjunct; RU 486.

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