INPLASY

Efficacy of Kuntai Capsule combined with low-dose Femoston in the treatment of perimenopausal syndrome: A meta-analysis

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Corresponding author:
Xiangnan Chen

2254475088@qq.com

Author Affiliation:
Heilongjiang University of Traditional Chinese Medicine.

Chen, XN; Wang, Y; Shi, BC; Xie, JM; Wu, XK.

ADMINISTRATIVE INFORMATION

Support - TCM evidence-based capacity improvement project [2023]2024;Heilongjiang Province Clinical Medical Research Center Project[LC2020R009]].

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2025110002

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 2 November 2025 and was last updated on 2 November 2025.

INTRODUCTION

Review question / Objective Review Objective: This systematic review and meta-analysis aims to evaluate the efficacy and safety of Kuntai Capsule combined with low-dose Femoston compared with low-dose Femoston alone for the treatment of perimenopausal syndrome in women.
Review Question:
P (Population): Women diagnosed with perimenopausal syndrome.
I (Intervention): Kuntai Capsule combined with low-dose Femoston.
C (Comparison): Low-dose Femoston alone.
O (Outcomes):Clinical efficiency rate,Kupperman scores,serum sex hormone levels(e.g,E2,FSH,LH),lipid profiles(e.g,TC,TG,LDL-C,HDL-C),endometrial thickness, incidence of adverse events.
S (Study Design): Randomized controlled trials.

Condition being studied Perimenopausal syndrome (PMS) is a clinical syndrome caused by the decline of ovarian function and the fluctuation of sex hormones in women before and after menopause. The common manifestations include hot flashes, sweating, insomnia, mood swings, memory loss, etc., which seriously affects the quality of life of patients.At present, hormone replacement therapy is a common means of relieving related symptoms. However, some patients still have concerns about the adverse reactions and limitations of steroid therapy alone.
Kuntai capsule, as a traditional Chinese medicine compound preparation, is composed of six Chinese herbs, Rehmanniae radix, Donkey-hide gelatin, Radix huangqin, Rhizoma coptidis, Radix paeoniae alba and Poria cocos. It has been widely used in the treatment of perimenopausal syndrome in China due to its natural composition and few side effects.
In recent years, although more and more clinical studies have explored Kuntai capsule combined

with low-dose femostone, their conclusions are inconsistent, resulting in a lack of systematic and clear evidence-based medical conclusions on the relative effectiveness and safety of this combination regimen.Therefore, the aim of this study is to systematically evaluate the efficacy and safety of Kuntai capsule combined with low-dose femostone compared with low-dose femostone alone in the treatment of perimenopausal syndrome women by Meta-analysis, in order to provide evidence-based basis for the prevention and treatment of PMS.

METHODS

Search strategy We searched PubMed, Web of Science, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI), China Biology Medicine (CBM), China Wanfang Data, and the China Science and Technology Journal Database (VIP).Randomized controlled trials of Kuntai Capsule combined with low-dose Femoston for perimenopausal syndrome from database inception until October 30, 2025.Using Chinese search terms such as "perimenopausal syndrome","perimenopausal","menopausal","climacteric","Kuntai Capsule","Femoston","randomized",ect.An example of English search strategy was Pubmed: ((((("Perimenopause"[Mesh]) OR (((Perimenopause[Title/Abstract]) OR (Climacteric[Title/Abstract])) OR (Menopause[Title/Abstract]))) AND (kuntai capsule[Title/Abstract])) AND ((Femoston[Title/Abstract]) OR (Estradiol[Title/Abstract] AND Dydrogesterone Tablets[Title/Abstract]))) AND (("Randomized Controlled Trial"[Publication Type]) OR (((random[Title/Abstract]) OR (blind[Title/Abstract])) OR (random*[Title/Abstract])))).A combination of subject headings and keywords was employed in all the aforementioned searches.

Participant or population Patients with perimenopausal syndrome were of any race, and all met the clinical diagnostic criteria for perimenopausal syndrome.

Intervention Kuntai capsule combined with low-dose femoston.

Comparator low-dose femoston.

Study designs to be included Randomized controlled trial.

Eligibility criteria Inclusion criteria:(1) The study type should be randomized controlled trial (RCT) with the word "randomized" mentioned, with no restriction on allocation concealment or blinding, and no restriction on the language of publication; All included studies were required to be accessible full-text literature.(2)Participants had to have a clinically confirmed perimenopausal syndrome.(3) Intervention measures:The specifications were as follows: Kuntai capsule, 0.5 g per capsule; Femoston, 1 mg/10 mg (i.e., the white tablet containing 1 mg of estradiol and the grey tablet containing 1 mg of estradiol and 10 mg of dydrogesterone).(4) The outcome measurement indicators should include at least one of the following: Clinical efficiency rate, Kupperman score, serum sex hormone levels (e.g.,E2, FSH, LH), lipid levels (e.g.,TC, TG, LDL-C, HDL-C), endometrial thickness, and adverse reactions.
Exclusion criteria: (1) Non-clinical randomized controlled trials that did not have a control group or used self-control or historical control studies.(2) Non-clinical studies such as animal experiments and in vitro research.(3) Case reports, reviews, commentaries, guidelines, conference abstracts, and literature that cannot be accessed in full text. (4) The intervention measures for the treatment group or the control group are unclear (such as the dosage and duration of the medication are unknown), or other Chinese or Western drugs or therapies that may affect the evaluation of the results have been used in combination.(5)Studies with missing data, substantial errors, or data that are significantly inconsistent with the reported conclusions, and for which complete data could not be obtained after contacting the original authors.

Information sources English database: PubMed, Web of Science, Embase, Cochrane Library.
Chinese database: China National Knowledge Infrastructure (CNKI), China Biology Medicine (CBM), China Wanfang Data, and the China Science and Technology Journal Database (VIP).

Main outcome(s) Clinical efficacy rate.

Additional outcome(s) Kupperman score, serum sex hormone levels (e.g.,E2, FSH, LH), lipid levels (e.g., TC, TG, LDL-C, HDL-C), endometrial thickness, and adverse reactions.

Data management Literature and data management were completed by two reviewers independently, including NoteExpress for literature duplication removal, literature screening according to inclusion and exclusion criteria, and pre-designed Excel for data extraction. Any disagreements arising during this process were resolved by mutual consultation, and if no

agreement could be reached, the decision was submitted to a third reviewer.

Quality assessment / Risk of bias analysis Cochrane TOOL.

Strategy of data synthesis RevMan5.4.1 and Stata 15.0software were used for statistical analysis. For dichotomous variables (including clinical response rate and adverse events), the Risk Ratio (RR) and 95% confidence interval (CI) were calculated as effect sizes.For continuous variables, the Mean Difference (MD) or Standardized Mean Difference (SMD) and their 95%CI will be combined, respectively, depending on their unit of measurement.
Heterogeneity between studies was assessed with the use of Cochran's Q test (with a test level of $P < 0.10$) and the I^2 statistic.If the heterogeneity was not significant ($P \geq 0.10$ and $I^2 < 50\%$), the fixed effect model was used. If there was significant heterogeneity ($P < 0.10$ or $I^2 \geq 50\%$), a random-effects model was used, and sensitivity or subgroup analyses were performed to explore the source of heterogeneity.We used the Z-test to determine the statistical significance of the summary effect, with a $P < 0.05$ deemed statistically significant.
When the number of studies included for a certain outcome indicator is no less than 10, a funnel plot will be used for visual inspection, and Egger's linear regression method will be employed to quantitatively assess the possibility of publication bias.

Subgroup analysis Subgroup analyses were performed according to factors such as intervention period, such as duration of treatment.

Sensitivity analysis The sensitivity analysis was analyzed by means of each study. If any research is removed, the overall conclusion does not have a substantial change, and it is confirmed that the combined results are robust and the sensitivity analysis is passed. This process targets the outcome indicators of significant heterogeneity ($I^2 \geq 50\%$).

Country(ies) involved China.

Keywords Kuntai Capsule; Femoston; Perimenopausal Syndrome; Efficacy; Safety; Meta-Analysis.

Contributions of each author
Author 1 - Xiangnan Chen.
Email: 2254475088@qq.com
Author 2 - Yu Wang.
Author 3 - Baichao Shi.
Author 4 - Jiumei Xie.
Author 5 - Xiaoke Wu.