INPLASY PROTOCOL

To cite: li et al. Meta analysis of Baogong Zhixue Granules in adjuvant treatment of dysfunctional uterine bleeding. Inplasy protocol 202240164. doi: 10.37766/inplasy2022.4.0164

Received: 28 April 2022

Published: 28 April 2022

Corresponding author:
LI Yue-wen

1297513234@qq.com

Author Affiliation:
Henan Province Hospital of TCM.

Support: **Henan Province Hospital of TCM.**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None declared.

Meta analysis of Baogong Zhixue Granules in adjuvant treatment of dysfunctional uterine bleeding

Li, YW[1]; Li, XZ[2]; Liu, ZQ[3]; Cui, XF[4].

Review question / Objective: **P (Population) : Patients who have been specifically diagnosed as dysfunctional uterine bleeding I (Intervention): Baogong Zhixue Granules combined with conventional Western medicine treatment C (Comparison): conventional Western medicine treatment O (Outcome): The total effective rate; Estradiol (E2) ; Pro-gesterone Prog (P); Follicle stimulating hormone (FSH); endometrial thickness; bleeding control time; fully hemostatic time; Hemoglobin (Hb) S (Study design): RCT.**

Condition being studied: **1.Dysfunctional uterine bleeding (DUB) is abnormal bleeding in the uterus caused by abnormal endometrial conditions or neuroendocrine dysfunction. Common in adolescent and Menopal women, clinical manifestations of irregular uterine bleeding, increased menstrual volume, some patients may be caused by excessive blood loss anemia, serious harm to patients' physical and mental health. The main clinical treatment is estrogen, progesterone and hysteroscopic surgery.However, the side effect of single hormone therapy is self-evident and has a high recurrence rate. Therefore, the clinical urgent need for combination of safe and effective treatment means, in order to fundamentally reduce patient pain. 2.Modern pharmacological research shows that baogongzhixue granule contains many kinds of bioactive substances, such as phenols, bioactive bases and glycosides, which can enhance uterine contraction, eliminate intrauterine remnants and enhance immune function. Meta analysis is used to provide a theoretical basis for clinical decision-making in the absence of systematic evaluation of the evidence for the use of dysfunctional uterine bleeding.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 April 2022 and was last updated on 28 April 2022 (registration number INPLASY202240164).

INTRODUCTION

Review question / Objective: **P (Population): Patients who have been specifically diagnosed as dysfunctional uterine bleeding I (Intervention): Baogong Zhixue Granules combined with conventional Western medicine treatment**

C (Comparison): conventional Western medicine treatment O (Outcome): The total effective rate; Estradiol (E2) ; Pro-gesterone Prog (P); Follicle stimulating hormone (FSH); endometrial thickness; bleeding control time; fully hemostatic time; Hemoglobin (Hb) S (Study design): RCT.

Condition being studied: 1.Dysfunctional uterine bleeding (DUB) is abnormal bleeding in the uterus caused by abnormal endometrial conditions or neuroendocrine dysfunction. Common in adolescent and Menopal women, clinical manifestations of irregular uterine bleeding, increased menstrual volume, some patients may be caused by excessive blood loss anemia, serious harm to patients'physical and mental health. The main clinical treatment is estrogen, progesterone and hysteroscopic surgery. However, the side effect of single hormone therapy is self-evident and has a high recurrence rate. Therefore, the clinical urgent need for combination of safe and effective treatment means, in order to fundamentally reduce patient pain. 2.Modern pharmacological research shows that baogongzhixue granule contains many kinds of bioactive substances, such as phenols, bioactive bases and glycosides, which can enhance uterine contraction, eliminate intrauterine remnants and enhance immune function. Meta analysis is used to provide a theoretical basis for clinical decision-making in the absence of systematic evaluation of the evidence for the use of dysfunctional uterine bleeding.

METHODS

Search strategy:
#1 "Dysfunctional uterine bleeding"[Mesh]
#2 "Baogong Zhixue Granules" OR "DUB" [Title/Abstract]
#3 "randomized, controlled trial "[MeSH Terms] OR "randomized controlled trial " [Title/Abstract] OR "clinical study" [Title/ Abstract] OR "clinical trial "[Title/Abstract]
#4 #1 OR #2 OR#3.

Participant or population: Patients who have been specifically diagnosed as dysfunctional uterine bleeding.

Intervention: Baogong Zhixue Granules combined with conventional Western medicine treatment.

Comparator: Conventional Western medicine treatment.

Study designs to be included: 1.Document retrieval2.Study Inclusion and exclusion 3.Determine outcome indicators 4.Bias Risk Assessment included in the literature 5.Extraction of outcome indicators 6.REVMAN 5.3 software was used for Meta analysis. 7.Discon and analysis of the results.

Eligibility criteria: (1) research data: Chinese and English RCT literature. (2) study subjects: Meet the diagnostic criteria of functional uterine bleeding in the textbook of Obstetrics gynecology and clinical guidelines for diagnosis and treatment. (3) intervention: The patients in the control group were given routine treatment of didroprovera tablets, desogestrel ethinylestradiol tablets, mifepristone tablets, etc. . The patients in the test group were given routine treatment combined with Baogongzhixue Granule.

Information sources: PubMed, CNKI, VIP, Wan Fang and other Data databases.

Main outcome(s): The total effective rate; Estradiol (E2) ; Pro-gesterone Prog (P); Follicle stimulating hormone (FSH) ; endometrial thickness; bleeding control time; fully hemostatic time; Hemoglobin (Hb).

Quality assessment / Risk of bias analysis: Two reviewers will independently assesses the quality of the selected studies accordin g to the Cochrane Collaboration's tool for r andomized controlled trials. Items will be e valuated in three categories: Low risk of bi as, unclear bias and high risk of bias. The f ollowing characteristics will be evaluated: Random sequence generation (selection Bi

as) Allocation concealment (selection bias) Blinding of participants and personnel (perf ormance bias) Incomplete outcome data (at trition bias) Selective reporting (reporting bi as) Otherbiases Results from these questio ns will be graphed and assessed using Revi ew Manager 5.3.

Strategy of data synthesis: Risk ratio (RR) for both fixed and random e ffects models (weighting by inverse of varia nce) will be used. A continuity correction wi ll also be used for cells with zero values. Be tween-study heterogeneity will be assessed using the T2,x= (Cochran Q) and I 2 statistics. According to the Cochrane han dbook, the 12 will be considered non-important (60%). Results will be assessed using forest plots and presented as RRs for the main outcome and secondary outcome s. An influence analysis will be performed t o ascertain the results of the meta-analysis by excluding each of the individual studies. Publication bias will be assessed by a funnel plot for meta-analysis and quantified by the Egger method. Statistical analysis will be conducted using STATA soft ware for Mac v15.0 (Stata Corp., College St ation, Texas) [module "meta"] and R studio v1.0.136 (The R Foundation for Statistical C omputing) [package "metaV4.2.

Subgroup analysis: We will consider Subgroup such as jurisdiction, clinic type, and location（rural\urban）.

Sensitivity analysis: In addition to funnel-plot analysis, rank correlation analysis, regression analysis and clipping-patch analysis are commonly used to detect publication bias. Of all the methods for identifying publication bias, the funnel diagram method is the most simple and practical, which can be used to judge directly whether the estimated effect value is related to the sample size or not, and to observe whether the distribution of the scatter diagram is symmetrical or not, to judge whether there is publication bias or not, but its disadvantage is that it is subjective and can not describe publication bias quantitatively, while rank correlation analysis, regression analysis and cut-and-complement analysis can describe publication bias quantitatively. If the publication bias is large, further measures should be taken to collect relevant information, such as contacting the original authors or the research team to find out whether there are studies with negative results, and if so, asking them to provide relevant information as far as possible. If the publication bias can not be reduced to a certain extent, the following measures should be considered: (1) sensitivity analysis should be used to test the stability of the effect estimation, if bias is found to significantly affect the findings of the systematic review, it should be reported as such and should be brought to the attention of the reader. (2) consider excluding low quality studies. Of course, the best way is to nip it in the bud. Researchers should establish a sound search strategy, find all published literature, actively seek unpublished or delayed published literature, and critically evaluate the quality of all research incorporated into the original study; Establish and improve the registration system of scientific research topics and fast access to published and unpublished literature; strengthen health research capacity and advocate the view that negative scientific research results are as important as positive results.

Country(ies) involved: China.

Keywords: Baogong zhixue granules; Dysfunctional uterine bleeding; Randomized controlled trial; Meta analysis Baogong zhixue granules; Dysfunctional uterine bleeding; Randomized controlled trial.

Contributions of each author:
Author 1 - liyuewen wen.
Author 2 - lixuezhu zhu.
Author 3 - liuzhiqiang qiang.
Author 4 - cuixuefeng feng.