INPLASY PROTOCOL

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None declared.

Efficacy and safety of Gushen Antai Pills combined with dydrogesterone in the treatment of threatened miscarriage: A Systematic Review and Meta-Analysis

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Review question / Objective: **This meta-analysis aimed to systematically evaluate the therapeutic effects of integrating Gushen Antai Pills and dydrogesterone in the treatment of threatened miscarriage.**
Condition being studied: **This meta-analysis was conducted to evaluate the efficacy and safety of integrated Gushen Antai Pills (GAP) and dydrogesterone in the treatment of threatened miscarriage (TM) from comprehensively summarizing available evidence, aiming to emphasize the therapeutic potential and mechanisms of integrating GAP and dydrogesterone and highlight its importance in treating TM at the clinical level. Moreover, this issue will provide better evidence to guide the rational therapy in clinical practice and develop the new clinical practice guidelines, further promoting the understanding and treatment for TM.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 December 2022 and was last updated on 09 December 2022 (registration number INPLASY2022120035).

INTRODUCTION

Review question / Objective: **This meta-analysis aimed to systematically evaluate the therapeutic effects of integrating Gushen Antai Pills and dydrogesterone in the treatment of threatened miscarriage.**

Rationale: **Gushen Antai Pills (GAP), a classic prescription of Traditional Chinese medicine (TCM) , has been widely used as an adjuvant therapy for treating threatened miscarriage (TM) in recent years. Although utilization of GAP in conjunction with dydrogesterone has a potentially beneficial effect in the treatment of TM, there is still a lack of systematic summary and analysis**

for its effectiveness and safety. This meta-analysis aimed to systematically evaluate the therapeutic effects of integrating GAP and dydrogesterone in the treatment of TM .

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METHODS

Search strategy: A systematic search of seven databases including PubMed, Cochrane Library, Embase, China National Knowledge Infrastructure (CNKI), the Chinese BioMedical database (CBM), Chinese Scientific Journal Database (VIP), and the Wanfang database was conducted to identify relevant studies. The retrieval deadline was July 19, 2022.The following medical subject heading (MeSH) terms and free-text terms individually or in all possible combinations: “threatened abortion” OR “threatened miscarriage” AND “dydrogesterone” OR “duphaston” AND “Gushen Antai”. In addition, we also reviewed the full-text articles designated for inclusion and manually checked the references of the retrieved articles to identify additional eligible studies.

Participant or population: Pregnant women with a viable pregnancy diagnosed with threatened miscarriage.

Intervention: Treatment with Gushen Antai Pills (GAP) combined with dydrogesterone.

Comparator: The control group was treated with dydrogesterone or progesterone alone.

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

Eligibility criteria: The exclusion criteria were as follows: (I) Repetitive published studies reporting the same data of patients; (II) Studies lacked the outcomes of interest; (III) Published abstracts and conference papers that did not provide full text and original data; (IV) Studies presenting incomplete data or data impossible to extrapolate or data with noticeable errors.

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Main outcome(s): The primary outcome was the incidence of early pregnancy loss. Secondary outcomes included serum progesterone, β-human chorionic gonadotropin (β-HCG), and estradiol (E2) levels ,as well as incidence of adverse reactions(AEs) and Alleviation of clinical symptoms.

Data management: Two researchers will independently screen and extract data based on the inclusion criteria and exclusion criteria. The disagreements were resolved by group consensus. First, The duplicates will be excluded initially. Second, reading the title and abstract to eliminate irrelevant records. Finally, after reading the full text of the remaining records, the appropriate studies will be included.Two reviewers will extract data using a standardized extraction form, including the basic information of the included studies. The following information

will be extracted: the first author, publication year, journal, study design, sample size, age, geographic population, experimental and control intervention, duration and follow-up, details of the risk of bias and outcomes.

Quality assessment / Risk of bias analysis: The quality of evidence will be independently evaluated using the Grading of Recommendations Assessment, Development , and Evaluation (GRADE) by two reviewers, evidence was classified as high, moderate, low, or very low based on the study limitations, inconsistency, indirectness, imprecision, and other factors./Two independent reviewers will assess the risk of bias of included RCTs according to the Cochrane Handbook[23], which includes random sequence generation, allocation concealment, blinding of participants, personnel and outcome assessors, incomplete outcome data, selective reporting, and other sources of bias. Any Disagreements between reviewers will be resolved by discussion or consultation with the third reviewer.

Strategy of data synthesis: RevMan 5.3 software (The Cochrane Collaboration, Copenhagen, Denmark) and Stata version 13.0 (Stata Corp LP) were used for the statistical analyses. Risk ratios (RRs) and 95% confidence intervals (CI) were assessed for dichotomous data, while standardized mean differences (SMD) or mean differences (MD) were used for continuous data. Heterogeneity was statistically assessed using the chi-squared test and the I2 statistic, and I2 > 50% indicated obvious heterogeneity among trials

Subgroup analysis: Subgroup analysis will be performed to explore the potential heterogeneity and inconsistency based on the different characteristics of participants.

Sensitivity analysis: To test the robustness of the pooled results, the sensitivity analysis will be conducted by eliminating one study each time or excluding studies with low quality.

Country(ies) involved: China.

Keywords: Threatened miscarriage; Gushen Antai Pills; Dydrogesterone; Complementary therapy; Meta-analysis.

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