

# INPLASY

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## The efficacy and safety analysis of integrated traditional Chinese and Western medicine in the treatment of threatened abortion with spleen and kidney deficiency-system review and meta-analysis

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### ADMINISTRATIVE INFORMATION

**Support** - None.

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

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202590113

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 September 2025 and was last updated on 27 September 2025.

### INTRODUCTION

**Review question / Objective** Systematic evaluation of the efficacy of integrated traditional Chinese and Western medicine in the treatment of threatened abortion with spleen and kidney deficiency. To provide evidence-based basis for the treatment of threatened abortion patients with spleen and kidney deficiency by integrated traditional Chinese and Western medicine.

**Condition being studied** Threatened abortion with spleen and kidney deficiency-system.

### METHODS

**Participant or population** Patients diagnosed with threatened abortion of spleen and stomach deficiency type.

**Intervention** The combination of traditional Chinese and Western medicine treatment of threatened abortion.

**Comparator** The control group was treated with simple western medicine / traditional Chinese medicine.

**Study designs to be included** Through systematic review and meta-analysis, this study sorted out the published randomized controlled trials of integrated traditional Chinese and Western medicine in the treatment of threatened abortion of spleen and kidney deficiency type and single treatment of threatened abortion, and discussed the effectiveness of integrated traditional Chinese and Western medicine in the treatment of threatened abortion of spleen and kidney deficiency type compared with single treatment.

**Eligibility criteria** Inclusion and Exclusion Criteria for Literature. Inclusion Criteria: (1) Study type: Randomized controlled trials published in Chinese and English literature. (2) Research subject: Patients diagnosed with threatened abortion of spleen and stomach deficiency type have detailed diagnostic basis. (3) Intervention measures: the combination of traditional Chinese and Western

medicine treatment of threatened abortion; the control group was treated with simple western medicine / traditional Chinese medicine. (4)Outcome indicators: clinical efficacy: effective rate, TCM syndrome score; sex hormone levels: HCG, E2, P; follow-up: pregnancy outcome, incidence of adverse reactions, etc.

Exclusion Criteria: (1) Research that cannot extract valid data; (2) Repetitively published literature; (3) Case reports, reviews, meeting abstracts, etc; (4) Animal experiment or corpse experiment.

**Information sources** Pub Med, EMbase, Cochrane, CNKI, VIP and Wanfang databases were systematically searched for studies on the treatment of threatened abortion with spleen and stomach deficiency by integrated traditional Chinese and Western medicine published before March 21,2025. Search terms included: ' Chinese traditional medicine ', ' Chinese herbal medicines ', ' traditional Chinese and western medicine '; 'Abortion, threatened ', ' threatened abortion ', ' threatened miscarriage '.

**Main outcome(s)** The 20 studies included in this study showed that the combination of traditional Chinese and Western medicine had a good clinical effect and maintenance effect in the treatment of threatened abortion. The results showed that the effective rate of integrated traditional Chinese and Western medicine in the treatment of threatened abortion was higher than that of single treatment, and the difference was statistically significant ( $P < 0.001$ ). In addition, the symptom scores of the patients in the treatment group were significantly lower than those in the control group, and this decrease was statistically significant ( $P < 0.001$ ), indicating that the combination of traditional Chinese and Western medicine can effectively promote the relief of symptoms. In addition, the comparison between the hormone levels of the treatment group and the control group further confirmed that the curative effect of the treatment group was more significant and statistically significant ( $P < 0.001$ ).

**Quality assessment / Risk of bias analysis** The Jadad scale was used to evaluate the quality of the included literature. The specific scores of the 20 articles included are as follows: a total of 4 articles with a score of 4-7 belong to high-quality literature, 1 research literature has a score of 6 points, and 3 articles have a score of 5 points; a total of 16 articles with a score of  $\leq 3$  belong to low-quality literature, including 16 articles with a score of 3. Generation of random sequences: 20 studies used randomization and described the correct randomization method. Randomization

concealment: 15 studies only described the use of random number method or random number table method and other random allocation schemes, but did not mention whether this method made clinicians and subjects unable to predict the allocation sequence. One study used opaque envelopes for randomization concealment, and three studies were controlled by computers. One study used blinding. Two studies described the number or reasons for withdrawal and loss of follow-up.

**Strategy of data synthesis** The Jadad scale was used to evaluate the quality of the included literature. Generation of random sequences: 20 studies used randomization and described the correct randomization method. Randomization concealment: 15 studies only described the use of random number method or random number table method and other random allocation schemes, but did not mention whether this method made clinicians and subjects unable to predict the allocation sequence. One study used opaque envelopes for randomization concealment, and three studies were controlled by computers. One study used blinding. Two studies described the number or reasons for withdrawal and loss of follow-up.

**Subgroup analysis** All studies included a total of about 1 611 participants (806 in the experimental group and 805 in the control group). Table 1 lists the basic characteristics of the included studies. The traditional Chinese medicine prescriptions in the experimental group mainly included Bushen Antai Decoction [21,23,26-29], Shoutai Pill [22,30-32], Bushen Jianpi Decoction [24,33-35], Baotai Decoction [20,36-40] and so on. The western medicine treatment measures in the control group were mainly dydrogesterone [21, 22, 24, 27, 28, 30, 32-35, 40] and progesterone [20, 23, 26, 29, 31, 36-39].

**Sensitivity analysis** The sensitivity analysis was performed to evaluate the stability of the summary results by excluding studies one by one. Potential publication bias was assessed by the significant asymmetry of the funnel plot and the Egger's test.

**Country(ies) involved** China.

**Keywords** Threatened abortion; Kidney diseases; Spleen; Integrative Medicine; Meta-analysis.

**Contributions of each author**

Author 1 - Mingchen Jin.

Author 2 - Ning Yang.

Author 3 - Jingya Liu.