INPLASY PROTOCOL

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Corresponding author:
Lingxia Xu

xulingxia94@163.com

Author Affiliation:
Academician Workstation, Jiangxi University of Chinese Medicine, Nanchang, Jiangxi, China.

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Conflicts of interest:
None declared.

Effect of Zishen Yutai Pill for the Treatment of Women with Threatened Miscarriage in First Trimester Pregnancy: a protocol of systematic review and meta-analysis

Xu, LX[1]; Wang, F[2]; Tu, Q[3]; Yan, DM[4]; Li, B[5]; Sun, P[6].

Review question / Objective: **P:Participants must be individuals diagnosed with threatened miscarriage. I: Zishen Yutai Pill combine with Western medicine. c: Western medicine. o:Human chorionic gonadotropin. S:All randomized controlled trials (RCTs) exploring the clinical outcomes of baotailing plus western medicine versus western medicine with TM in woman were included.**
Condition being studied: **Zishen Yutai Pill is a complementary medical treatment primarily practiced in China and is believed to have tonifying the kidney effects.14. Animal study confirmed that TCM of Tonifying the kidney and fetus protected the embryo by regulating the increase of vascular endothelial growth factor (VEGF) and enhancing the expression of VEGFR2 mRNA and protein15. Based on this, The systematic review was performed to evaluate the efficacy and safety of Zishen Yutai Pill used for TM in first trimesterpregnancy.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 February 2023 and was last updated on 09 February 2023 (registration number INPLASY202320039).

INTRODUCTION

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METHODS

Participant or population: Participants must be individuals diagnosed with threatened miscarriage.

Intervention: Eligible interventions were Zishen Yutai Pill combined with Western medicine.

Comparator: Western medicine.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: All randomized controlled trials (RCTs) exploring the clinical outcomes of Zishen Yutai Pill plus western medicine versus western medicine with TM in woman were included.

Information sources: PubMed, EMBASE, web of science, Cochrane Library, China National Knowledge Infrastructure (CNKI), Wan Fang Database (WanFang), sinomed and Weipu Database for Chinese Technical Periodicals (VIP).

Main outcome(s): Human chorionic gonadotropin ((IU/ml)) was considered as the primary outcome.

Quality assessment / Risk of bias analysis: RevMan Manager 5.3 software was used to evaluate the risk of bias of including studies. which including seven items. We measured trial quality using seven domains: random sequence generation; allocation concealment; blinding of patients and doctors; blinding of outcome assessment; incomplete and missing outcome data; selective outcome data reporting, other bias.

Strategy of data synthesis: Data from individual RCTs were combined in the meta-analysis using the random effects model. Continuous variables use mean difference (MD) or standardized mean difference (SMD) as the effect quantity, and rank variables use odds ratio (OR) or relative risk (RR) as the effect quantity. 95% confidence interval (CI) is calculated for both. the chi-squared test and I2 values was used to assess statistical heterogeneity, with significance levels of P > 0.1 and I2>50%, respectively.

Subgroup analysis: Subgroup analyses stratified by treatment time.

Sensitivity analysis: When the number of studies is ≥ ten, funnel plots and Egger's tests was used to detect publication bias for outcomes.

Country(ies) involved: China.

Keywords: Zishen Yutai pill, threatened miscarriage, first-trimester pregnancy, systematic review, meta- analysis.

Contributions of each author:
Author 1 - LINGXIA XU.
Email: xulingxia94@163.com
Author 2 - fei wang.
Email: skywf@163.com
Author 3 - qing tu.
Email: 2720477121@qq.com
Author 4 - dongmei yan.
Email: yandongmei2021@outlook.com
Author 5 - bin li.
Email: bin2021li@outlook.com
Author 6 - peng sun.
Email: xlx1992a@126.com

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