INPLASY PROTOCOL

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None declared.

Efficacy and safety of Yunkang oral liquil combined with conventional therapy for threatened miscarriage of first-trimester pregnancy A protocol for systematic review and meta-analysis

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Review question / Objective: **Is Yunkang oral liquid effective and safe in adjuvant treatment of threatened miscarriage of first-trimester pregnancy?**
Condition being studied: **Threatened miscarriage (TM), as a common complication of first-trimester pregnancy, occurring in 30% to 40% of all clinically recognized pregnancies, brings heavy medical and economic burdens to female patients. Currently, due to many high-profile benefits, clinical studies on Yunkang oral liquil(YKOL) have been increasing. Yunkang oral liquil is a TCM prepation made of common yam rhizome, himalayan teasel root, milkvetch root, Chinese angelica, East Asian Tree Fern, Rhizome, dodder seed, Chinese taxillus herb, Eucommia ulmoides, malaytea scurfpea fruit, tangshen, Indian bread, Laragehead Atractylodes Rhizome, ass hide glue, Rehmannia Glutinosa, Asiatic Cornelian Cherry Fruit, Babury Wolfberry Fruit, smoked plum, White Paeony Root, Villous amomum fruit, sharp-leaf glangal fruit, Ramie Root, baical skullcap root, Argy Wormwood Leaf through chemical extraction and refinement. Thus, the aim of the study is to assess the efficacy and safety of YKOL in the treatment of threatened miscarriage of first-trimester pregnancy(TMFP).**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 April 2021 and was last updated on 21 April 2021 (registration number INPLASY202140105).

INTRODUCTION

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METHODS

Search strategy: The proposed database search using the medical subjective headings (MeSH) search terms: [(threatened miscarriage OR miscarriage OR threatened abortion OR abortion OR pregnant loss) AND (progesterone OR progestin OR dydrogesterone OR choriogonadotrophin OR chorionic gonadotropin OR chorionic gonadotropic hormone OR phloroglucin OR allylestrenol OR western medicine) AND (randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR) AND (randomly [tiab] OR trial [tiab] OR groups [tiab]) AND (animal[mh] NOT humans[mh]) AND (Yunkang oral liquil)].

Participant or population: Types of participants : The eligible patients in term of the diagnostic criteria for early threatened miscarriage of the 6th Edition of Gynecology and Obstetrics the diagnostic, and the female patients must be older than 18 years old.

Intervention: Bed rest, prohibitions of sexual life, the use of human chorionic gonadotropin (hCG), uterine muscle relaxants, progestogens, vitamin E, and other drugs.

Comparator: Bed rest, prohibitions of sexual life, the use of human chorionic gonadotropin (hCG), uterine muscle relaxants, progestogens, vitamin E, and other drugs.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: The eligible patients in term of the diagnostic criteria for threatened miscarriage of first-trimester pregnancy(TMFP) of the 6th Edition of Gynecology and Obstetrics the diagnostic . And the female patients must be older than 18 years old.

Information sources: Literature databases: PubMed, EMBASE, CENTRAL, China Biomedical Literature Database, Chinese National Knowledge Infrastructure, Wanfang Data, and VIP Trial registry: Clinicaltrials.gov, and Chinese Clinical Trial Registry. Source of grey literature: reference lists of relevant reviews.

Main outcome(s): The incidence of miscarriage.

Additional outcome(s): The total effective rate(TER), Human chorionic gonadotropin (HCG), progesterone(P), estradiol(E2), abdominal pain, Vaginal bleeding, lumbago, Adverse reactions.

Data management: The following information from the selected studies will be summarized in a unified table: 1) basic information of the ultimate eligible studies: first author's last name, time of publication, first author's country, diagnostic criteria, inclusion criteria, exclusion criteria, and sample size; 2) baseline characteristics of the patients: mean baseline age, treatment period, time of pregnancy, obstetric and

gynecological history, basic therapies; 3) treatment and control measurements: the dosage of YKOL, the duration of treatment; 4) outcomes: baseline and follow-up data; 5) adverse effects.

Quality assessment / Risk of bias analysis: Risk of bias for the included RCTs will be assessed by Review Manager 5.3. Evaluation items are as follows: 1) whether random sequences are generated; 2) whether distribution is hidden; 3) whether participator and researchers are blinded; 4) whether study outcomes are blind; 5) whether outcome data is missing; 6) whether the report is selective; 7) other sources of bias. Summary of each item results with a high, low, or unclear risk of bias will be displayed as a table. Two investigators will independently assess the quality of the included studies, and disagreement in risk of bias will be resolved by three investigators through consultation.

Strategy of data synthesis: RevMan 5.4.1 will be used for data analysis. Odds ratio (OR) or relative risk (RR), 95% Confidence interval (CI) and P values will be used to estimate dichotomous variables include. The continuous data will be analyzed by Mean difference (MD) or Std Mean difference (SMD), 95% Confidence interval (CI) and P values. Concurrently, The Q value test and I2 index was used to measure the statistical heterogeneity. The meta-analyses will be based on the random effects model, Otherwise, a fixed effect model will be adopted.

Subgroup analysis: If we find substantial heterogeneity, the grouping factor for Subgroup analysis will be executed according to therapy time.

Sensitivity analysis: Sensitivity analysis will be performed by excluding studies with high risk of bias and change the statistical model.

Country(ies) involved: China.

Keywords: Yunkang oral liquil(YKOL); threatened miscarriage of first-trimester pregnancy(TMFP); protocol; systematic review.

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