INPLASY PROTOCOL

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None declared.

Efficacy and safety of Chaihu Guizhi Decoction in the treatment of climacteric syndrome: A protocol for systematic review and meta-analysis

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Review question / Objective: **The main purpose of this study is to use evidence-based medicine methods to systematically evaluate the difference in efficacy between CGD and MHT in the treatment of CS, in order to provide guidance for clinical practice.**
Condition being studied: **Menopause is an inevitable stage in the growth process of women, but the symptoms of climacteric syndrome (CS) can be painful, the current treatment is commonly used menopause hormone therapy (MHT). The Chaihu Guizhi decoction (CGD) is a traditional East Asian medicine , a number of Randomized Controlled Trials proved that CGD alleviates the symptoms of CS significantly and has fewer side effects than MHT. Therefore, we have outlined a plan to explore the efficacy and safety of Chaihu Guizhi decoction in the treatment of female menopausal syndrome.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 April 2021 and was last updated on 23 April 2021 (registration number INPLASY202140118).

INTRODUCTION

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METHODS

Participant or population: All patients who met the standard for CS(as diagnosed using any authoritative diagnostic criteria) diagnosis will be included, regardless of weight, sex, race, age, duration of disease, or education.

Intervention: The treatment group is any dosage form of prescription CGD, including water decoction, granule, capsule.The treatment group is any dosage form of prescription CGD, including water decoctiongranule, capsule.

Comparator: The control group took menopause hormone therapy and other conventional Western medicine treatments.

Study designs to be included: This study will search for all RCTs that have been published in English and Chinese about CGD treatment of CS, regardless of whether the blind method and allocation concealment are used.

Eligibility criteria: All patients who met the standard for CS(as diagnosed using any authoritative diagnostic criteria) diagnosis will be included, regardless of weight, sex, race, age, duration of disease, or education.

Information sources: We will search for related documents in the following 7 databases: Embase, PubMed, Cochrane Library, China National Knowledge Infrastructure (CNKI), China Biology Medicine disc (CBMdisc), China Science Periodical Database (CSPD), and Chinese Scientific Journal Database (VIP database), from establishment to April 2021. The search will be carried out in the form of a combination of free words and medical subject words, including “climacteric syndrome”, “Climacterics”, “Change of Life”, “Life Change”, “Life Changes”, "chaihu guizhi decoction" "CHGZT" "CGD" "Chai-Hu-Gui-Zhi-Tang" "Bupleuri and Ramuli Cinnamomi Decoction" "Chaihuguizhi" "Chaihu Guizhi soup" “randomized controlled,” “randomized controlled trial,” “clinical trial” “randomized, controlled”. We will be retrieved in the Chinese database with the same Chinese search terms. At the same time, we will manually search for unpublished research experiments and references.

Main outcome(s): (1) Analyze the improvement of related indicators after the intervention of the two groups of subjects.Specifically, it contains luteinizing hormone, estradiol, and follicular estrogen. (2) Symptom Kupperman score, analyze the details of the comparison of treatment effects between the two groups of subjects.Each symptom is divided into no, mild, moderate, and severe according to the degree, corresponding to 0 to 3 points respectively.The product of the coefficient and the degree of each symptom is the Kupperman symptom score, and the sum of the symptom scores is the total score.

Quality assessment / Risk of bias analysis: Two rigorously trained researchers independently evaluated the methodological quality of the included literature based on the bias risk assessment tool. The Newcastle-Ottawa Scale is used to evaluate the quality of selected RCTs. The scale contains two major contents that are applicable to cohort studies and case-control studies. The cross-sectional research was evaluated using the literature quality evaluation standards for cross-sectional research recommended by the Agency for Healthcare Research and Quality in the United States.

Strategy of data synthesis: First use RevMan5.3.5 software to evaluate the

magnitude of data synthesis, I2＜50% believes that there is no statistical heterogeneity or small heterogeneity between the studies, and the fixed-effects model is used to merge the data; I2> 50% believes that there is a certain degree of heterogeneity between the studies, and the random effects model is used to merge the effect sizes; If heterogeneity is found, sensitivity analysis or subgroup analysis is performed to determine the source of heterogeneity; If there are more than 10 studies included for a certain outcome index, use an inverted funnel chart to analyze whether there is publication bias.

Subgroup analysis: If necessary, subgroup analyses will be performed according to the different types of participant characteristics, treatment methods, treatment frequency, and so on.

Sensitivity analysis: When the heterogeneity is found, the RevMan5.3 software software is used to analyze the sensitivity of the source of the heterogeneity by eliminating the literature one by one.

Country(ies) involved: China.

Keywords: Chaihu Guizhi decoction, protocol, climacteric syndrome, systematic review.

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