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Clinical efficacy of "Sancai therapy" for hyperplasia of the mammary glands: A systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Formal screening of search results against eligibility criteria.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202380124

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 August 2023 and was last updated on 30 August 2023.

INTRODUCTION

Review question / Objective The purpose of this study aimed to evaluate the clinical efficacy of Sancai therapy compared to conventional therapy in the treatment of Hyperplasia of the mammary glands(HMG). The method of the study was RCT experiment and the patients were diagnosed with HMG according to clinical diagnostic criteria.The outcome indicators were the overall efficacy, clinical cure rate, breast pain score, and breast mass score.

Condition being studied In this study, two researchers independently screened the literature, extracted the data, and imported the data into RevMan 5.4.1 software for Meta-analysis, and used the "Risk of Bias" tool in the software to evaluate the methodological quality of the included literature, and a third researcher supervised and managed the management.

METHODS

Participant or population patients were diagnosed with HMG according to clinical diagnostic criteria.

Intervention The treatment group received Sancai therapy alone or in combination with other control therapies.

Comparator The control group was treated with the patent TCM drugs alone, TCM decoctions, Western medicine, or a combination of TCM and Western medicine.

Study designs to be included RCT.

Eligibility criteria Patients were diagnosed with HMG based on the criteria outlined in the "TCM Disease Diagnostic and Therapeutic Criteria" and "Diagnosis and Treatment of Hyperplasia of the Mammary Glands" issued by the National

Administration of Traditional Chinese Medicine, and the "Diagnostic Criteria for Hyperplasia of the Mammary Glands" issued by the Mammary Gland Disease Committee of the Chinese Association of Traditional Chinese Medicine and Surgery, or through clinical examinations such as breast ultrasonography or mammography.

Information sources We searched the Chinese (CNKI, VIP, Wanfang Data, and SinoMed) and English (PubMed, Web of Science, EMBASE, and Cochrane Library) databases.

Main outcome(s) The outcome indicators were the overall efficacy, clinical cure rate, breast pain score, and breast mass score.

Quality assessment / Risk of bias analysis Two investigators used the "risk of bias assessment" tool in RevMan 5.4.1 software to evaluate the methodological quality of the included articles, and assessed them as "low risk," "unclear," or "high risk." The assessments included random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and selective reporting of study results.

Strategy of data synthesis The included articles underwent data analysis using RevMan 5.4.1 software, in accordance with the PRISMA guidelines. The relative risk (RR) of binary variables was expressed as the effect size with a 95% confidence interval (CI). Continuous variables were expressed as standardized mean difference (SMD) with 95% CI. For studies with multistage reporting, only results from the last stage were selected. Study heterogeneity was evaluated using the I2 test. A $p > 0.1$ and $I2 \leq 50\%$ indicated good homogeneity among studies, and the fixed-effect model was used. When $p \leq 0.1$ and $I2 > 50\%$ indicated significant heterogeneity among studies, and the random-effects model was used. In cases of high heterogeneity, the source was examined through subgroup or sensitivity analyses (individual exclusion of articles). Additionally, when at least ten articles were included as outcome indicators, funnel plots were constructed to test for publication bias.

Subgroup analysis No subgroup analysis in this study.

Sensitivity analysis Sensitivity analysis using RevMan 5.4.1 software to reflect the sensitivity of an article by the change in effect size after deletion of that article.

Country(ies) involved China.

Keywords Sancai therapy; hyperplasia of the mammary glands (HMG); clinical efficacy; meta-analysis.

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