

# INPLASY PROTOCOL

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**Corresponding author:**  
Zhe rui Peng

3099307112@qq.com

**Author Affiliation:**  
Wuhan university.

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**Conflicts of interest:**  
None declared.

## Systematic Review of Xiaojiean Jiaonang on Clinical Effect for Treatment on Mammary Gland Hyperplasia

Peng, ZR<sup>1</sup>; Qiu, JF<sup>2</sup>.

**Review question / Objective:** Hyperplasia of mammary glands is a common breast disease with lumps, swelling and pain in the breast as the main manifestation. Mammary hyperplasia is more common in middle-aged women aged 25 to 45 years old and ranks first in breast diseases, with a trend of younger growth in recent years. The purpose of this study is to systematically evaluate the effectiveness of the Xiaojiean Jiaonang in the treatment of hyperplasia of mammary glands. The type of studies included in this study is randomized controlled trials.

**Information sources:** Search PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, EMBASE, CBM, CNKI, VIP and Wanfang databases were searched by computer. The search date was set to 31 January 2022. According to the needs of different databases, corresponding retrieval formats were adopted.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 January 2022 and was last updated on 18 January 2022 (registration number INPLASY202210096).

### INTRODUCTION

**Review question / Objective:** Hyperplasia of mammary glands is a common breast disease with lumps, swelling and pain in the breast as the main manifestation. Mammary hyperplasia is more common in

middle-aged women aged 25 to 45 years old and ranks first in breast diseases, with a trend of younger growth in recent years. The purpose of this study is to systematically evaluate the effectiveness of the Xiaojiean Jiaonang in the treatment of hyperplasia of mammary glands. The type

of studies included in this study is randomized controlled trials.

**Condition being studied:** Hyperplasia of mammary gland is the most common breast disease. Anti estrogen therapy is mainly used in clinic, but it will cause a series of gynecological diseases such as ovarian tumor, amenorrhea and menstrual disorder. Xiaojiean Jiaonang is composed of 6 Dai drugs, which has the effects of promoting blood circulation and removing blood stasis, clearing heat and detoxification, softening hardness and dispersing knot. This study uses the method of systematic evaluation to analyze the effectiveness of Xiaojiean Jiaonang in the treatment of breast hyperplasia, and uses the grade system to make the level of evidence and recommendation, in order to provide more reliable evidence-based medical evidence for the treatment of breast hyperplasia by traditional Chinese medicine.

## METHODS

**Participant or population:** Patients with hyperplasia of mammary glands

**Intervention:** The experimental group was treated with Xiaojiean capsule or other Western medicine, with unlimited course and dose.

**Comparator:** The control group was treated with the same Western medicine as the treatment group, or other proprietary Chinese medicine and placebo

**Study designs to be included:** RCT.

**Eligibility criteria:** Inclusion criteria: the included studies were randomized controlled trials with no restriction on whether or not they were blinded. Patients with a definite diagnosis of hyperplasia of mammary glands were recruited with no limitations regarding age, disease course or source of cases. Exclusion criteria: 1. Non randomized controlled trials, all trials with their own before and after control or no controlled experiments. 2. Studies without definite diagnostic criteria,

inclusion and exclusion criteria. 3. Trial design is not rigorous or the process is not clear. 4. Review, preventive studies, animal experiments, conference proceedings, summary of personal experience, discussion of other non clinical trials and duplicate published studies.

**Information sources:** Search PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, EMBASE, CBM, CNKI, VIP and Wanfang databases were searched by computer. The search date was set to 31 January 2022. According to the needs of different databases, corresponding retrieval formats were adopted.

**Main outcome(s):** 1. Clinical efficacy of patient treatment, 2 The diameter and area of the breast mass; 3. Hormone levels of luteinizing hormone (LH), estradiol (E2), progesterone (P) and prolactin (PRL).

**Quality assessment / Risk of bias analysis:** The criteria for the study quality evaluation of included RCTs used the Cochrane Collaboration 'risk of bias' evaluation tool. The content of the review included the following: method of randomization, allocation concealment of randomization protocol, blinding (including operator and subject blinding and outcome reviewer blinding), whether outcome data were fully reported (loss to follow-up or withdrawal, if there was loss to follow-up or withdrawal, whether intention to treat analysis was used), selective outcome reporting, and whether there was any other bias (completeness of information on baseline data for the main review). Each entry was reported according to the following criteria: low risk of bias, high risk of bias. Risk, unclear risk of bias.

**Strategy of data synthesis:** Statistical analysis of the data was performed using the cochrane collaboration Review Manager 5.3 software, dichotomous variables, count data were expressed as odds ratio (OR), and 95% confidence interval (CI) was calculated, first the data of the studies were analyzed for heterogeneity, the appropriate model for

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statistical analysis was selected, when  $I^2 > 50\%$  was included in the study heterogeneity test, there was no heterogeneity, Using a fixed effects model) analysis; When the  $I^2$  of heterogeneity test among included studies was  $< 50\%$ , there was heterogeneity, which was analyzed by random effects model, and the potential publication bias was analyzed by "" inverted funnel "" analysis with the testing level  $\alpha = 0.05$ .

**Subgroup analysis:** When significant heterogeneity exists (e.g., age, marital status, publication year, etc.), subgroup analysis will be performed to identify the source of heterogeneity.

**Sensitivity analysis:** After deleting any article, the time difference between the combined results of other literatures and those not deleted is not large, which means that the sensitivity analysis has been passed.

**Country(ies) involved:** China.

**Keywords:** Xiaojiean Jiaonang; Hyperplasia of mammary glands.

**Contributions of each author:**

Author 1 - Zherui Peng.

Author 2 - Jiefan Qiu.