INPLASY PROTOCOL

To cite: Yang et al. Effectiveness and safety of Pingxiao Capsule adjuvant chemotherapy in the treatment of breast cancer: A Meta-analysis. Inplasy protocol 202260047. doi: 10.37766/inplasy2022.6.0047

Received: 11 June 2022

Published: 11 June 2022

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Support: **2018ZY1007; 19A360015.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None declared.

Effectiveness and safety of Pingxiao Capsule adjuvant chemotherapy in the treatment of breast cancer: A Meta-analysis

Yang, YQ[1]; Chen, YH[2]; Li, CX[3]; Ling, X[4]; Wang, PP[5]; Guo, J[6]; Zhang, YY[7];

Review question / Objective: **This study systematically evaluated the efficacy and safety of Pingxiao Capsules adjuvant chemotherapy in the treatment of breast cancer. The subjects of the study were patients with a clinical diagnosis of breast cancer. The included studies were randomised controlled trials. The experimental group was given Pingxiao capsule combined with chemotherapy, while the control group was given chemotherapy alone. The primary outcomes were objective response rate and disease control rate. Secondary outcomes included quality of life, immune cells, white blood cell counts, and adverse effects.**
Condition being studied: **Breast cancer is one of the most common malignant tumor in women, with high morbidity and mortality. GLOBOCAN global cancer statistics in 2021 indicated that the number of new breast cancer cases in the world have reached 2.26 million, suggesting that breast cancer has officially become the largest cancer in the world. In China, the incidence of breast cancer is also increasing year by year. In 2015, approximately 304,000 new breast cancer cases have been reported in China; by 2020, the number of new breast cancer cases has risen to 420,0008, ranking first among Chinese female malignant tumors.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 June 2022 and was last updated on 11 June 2022 (registration number INPLASY202260047).

INTRODUCTION

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METHODS

Search strategy: The search method of "subject heading + free word" was preferred. The Chinese search terms included “Pingxiao Capsule” and “Breast Cancer”, and the English search terms included “Pingxiao” + “Breast Cancer” or “Breast Neoplasm” or “Mammary Cancer” or “Breast Malignant Neoplasm” or “Breast Carcinoma” or “Breast Malignant Tumor”.

Participant or population: Breast cancer patients diagnosed histopathologically or cytologically.

Intervention: Pingxiao capsule combined with chemotherapy.

Comparator: Chemotherapy alone, the chemotherapy including capecitabine, letrozole, tamoxifen, CAF regimen, and FEC regimen.

Study designs to be included: Randomized controlled trial (RCTs).

Eligibility criteria: Studies meeting the following criteria were excluded: (1) Non-RCT studies (basic research, systematic review, meta-analysis, review, case report, ect); and duplicate studies; (2) other traditional Chinese medicines were used during treatment; (3) The outcome indicators were not included in the research indicators; (4) studies enrolling patients with other malignancies; (5) studies without statistical data; and (6) studies with incomplete data.

Information sources: Eight databases including The Cochrane Library, PubMed, EMBASE, EI, CBM, Wan fang, CNKI and VIP Database were searched.

Main outcome(s): The primary outcomes were objective response rate and disease control rate. The secondary outcomes included the quality of life, immune cells, white blood cell count, and adverse reactions.

Quality assessment / Risk of bias analysis: the Cochrane Risk of Bias Tool1.0 (RoB1.0).

Strategy of data synthesis: R language was used for estimating risks of bias of included studies, data analysis, sensitivity analysis, the publication bias test, and plotting. The Chi-square tests and I2 were used for estimate heterogeneity. If $P \geq 0.1$ or $I2 \leq 50\%$, fixed effect model was used for analysis; if P50%, random effect model was used. The experimental group (Pingxiao capsule plus chemotherapy) and control group (chemotherapy alone) were calculated and compared. Mean difference (MD) or standard mean difference (SMD) was used for analysis of continuous data, and rate ratio (RR) with a 95% CI was used for the dichotomous variable. $P<0.05$ was considered to be statistically significant. When the number of included studies was more than 10, funnel plot and egger's test were used for estimation of publication bias.

Subgroup analysis: A subgroup analysis of immune cells, white blood cell counts, and adverse reactions among secondary outcome indicators was planned.

Sensitivity analysis: Sensitivity analysis was performed using R software to express the sensitivity of an article by removing changes in the effect size of an article.

Country(ies) involved: China.

Keywords: Pingxiao capsule; Breast cancer; Meta-analysis; Randomized controlled trial (RCT).

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