

INPLASY PROTOCOL

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None declared.

Efficacy and safety of trastuzumab combined with neoadjuvant chemotherapy in Chinese patients with HER-2 positive breast cancer: a meta-analysis

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Review question / Objective: To systematically evaluate the efficacy and safety of docetaxel combined with carboplatin and trastuzumab (TCH) neoadjuvant chemotherapy in Chinese patients with HER2-positive breast cancer.

Condition being studied: Chinese patients who have been clinically diagnosed as HER-2 positive breast cancer, not complicated with basic diseases such as heart, liver and bone marrow, and who have received established surgery after chemotherapy and cooperated with follow-up.

Eligibility criteria: Non-randomized controlled trials, animal experiments, literature review, non-docetaxel combined with carboplatin and trastuzumab as adjuvant therapy in Chinese breast cancer patients, and other drugs used in the intervention group or control group.

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INTRODUCTION

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METHODS

Search strategy: Chinese patients with HER-2 positive breast cancer (731).

Participant or population: Docetaxel combined with carboplatin and trastuzumab.

Intervention: docetaxel combined with carboplatin and trastuzumab.

Comparator: docetaxel combined with carboplatin.

Study designs to be included: There are randomized controlled trials of trastuzumab combined with neoadjuvant chemotherapy in Chinese patients with HER-2 positive breast cancer, blinded or not.

Eligibility criteria: Non-randomized controlled trials, animal experiments, literature review, non-docetaxel combined with carboplatin and trastuzumab as adjuvant therapy in Chinese breast cancer patients, and other drugs used in the intervention group or control group.

Information sources: PubMed, Embase, Cochrane Library, Wanfang Medical, VIP and CNKI were searched from the establishment of the database to September 2022.

Main outcome(s): The total effective rate of trastuzumab combined with neoadjuvant chemotherapy in Chinese patients with HER2-positive breast cancer was significantly higher than that of docetaxel combined with carboplatin (TC) (OR=3.07, 95%CI 2.11-4.46, P<0.00001), and subgroup analysis showed that there was no difference in the improvement of total effective rate between north and south in China. Meta-analysis also showed that the negative rate of HER-2 and pathological effective rate in the observation group were higher than those in the control group. (OR=2.73, 95%CI 1.48-5.03, P=0.001) , (OR=2.68, 95%CI 1.59-4.52, P=0.0002). In addition, there was no significant difference in the adverse reaction rate

between the observation group and the control group.

Quality assessment / Risk of bias analysis: Nine articles included in the study were evaluated using the bias risk tool in the Cochrane manual. The overall quality of the selected articles was good. There were a large number of people (>5%) who had not completed the trial in one study, and three studies did not specifically mention the generation method of random sequence, which was considered as medium risk; Uncertainty about whether there are other sources of bias in the included study is a medium risk; The rest are low risk.

Strategy of data synthesis: The statistical software RevMan5.3 was used for analysis, and the dichotomous variables were expressed by odds ratio (OR) and 95% confidence interval (CI). To stabilize the baseline and reduce the source of heterogeneity, subgroup analysis could be performed according to the appropriate variable grouping. Chi-square test was used to determine the heterogeneity of the included studies. When P>0.1 and I²≤50%, the homogeneity among the studies was good, and the fixed effect model was used for meta-analysis. When P≤50%, there was heterogeneity among the studies, and further sensitivity analysis was needed to find the source of heterogeneity. If there was no obvious clinical heterogeneity, the fixed effect model was selected for merging. If the heterogeneity was large, meta-analysis was not performed, and only descriptive studies were performed.

Subgroup analysis: The total effective rate of trastuzumab combined with neoadjuvant chemotherapy in Chinese patients with HER2-positive breast cancer was significantly higher than that of docetaxel combined with carboplatin (TC) (OR=3.07, 95%CI 2.11-4.46, P<0.00001), and subgroup analysis showed that there was no difference in the improvement of total effective rate between north and south in China.

Sensitivity analysis: Literature was retrieved to extract the incidence data of

adverse reactions, and the incidence of gastrointestinal reactions, cardiotoxicity and liver function damage were analyzed by fixed-effect model. Random effect model was used to analyze the incidence of myelosuppression ($P=0.02$, $I^2=59\%$), indicating heterogeneity. Sensitivity analysis excluded 1 article ($P=0.36$, $I^2=10\%$), and the rest of the articles were homogenous, and the fixed effect model was used to analyze. All the four results showed that there was no significant difference in the adverse reaction rate between the observation group and the control group.

Country(ies) involved: China.

Keywords: carboplatin; docetaxel; trastuzumab; breast cancer; meta analysis.

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