INPLASY

INPLASY2023120048

doi: 10.37766/inplasy2023.12.0048

Received: 11 December 2023

Published: 11 December 2023

Study on the efficacy and safety of Huangqi Guizhi Wuwu Decoction in the prevention and treatment of Chemotherapy-induced peripheral neuropathy

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ADMINISTRATIVE INFORMATION

Support - Innovative subject of Scientific Research practice of College students in Chengdu University of traditional Chinese Medicine from 2023 to 2024(ky-2024041).

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023120048

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 December 2023 and was last updated on 11 December 2023.

INTRODUCTION

Review question / Objective P：Patients who have been confirmed as malignant tumors by histopathology and / or cytology or imaging examination and have been treated with drugs that are currently known to cause chemotherapy-induced peripheral neuropathy (There are no restrictions on tumor type and stage, age, race and sex）.

I：On the basis of routine chemotherapy, Huangqi Guizhi Wuwu decoction or Huangqi Guizhi Wuwu decoction combined with positive drugs were used.

C：The control group was given blank control, or placebo control, or positive drug control alone (duloxetine or mecobalamin) on the basis of routine chemotherapy.

O：

1.The main outcome indicators: Total Incidence of CIPN; Incidence of sever CIPN (level 3 or above). Total effective rates; EORTC QLQ-CIPN20 scale;

2.The secondary outcome indicators: sensory nerve conduction velocity (median nerve and peroneal nerve), Karnofsky performance score(KPS) and Adverse events Related to treatment.

S：Randomized controlled clinical trial (RCT).

Condition being studied Huangqi Guizhi Wuwu （HGWD） decoction is a classic prescription for the treatment of Chemotherapy-induced peripheral neuropathy(CIPN) with traditional Chinese medicine. Modern pharmacology shows that Huangqi Guizhi Wuwu decoction may improve CIPN by down-regulating the expression of NR2B in L4-6 spinal cord and up-regulating the level of pNF-H protein in DRG. In view of its potential benefits, HGWD has a great prospect in the

treatment of CIPN. However, the lack of large samples and evidence-based research hinders its promotion and application. Therefore, the purpose of this study is to evaluate the efficacy and safety of HGWD in the treatment of CIPN through Meta analysis of randomized controlled trials.

METHODS

Participant or population Patients with malignant tumors confirmed by histopathology and / or cytology or imaging examination.Chemotherapy regimens involve the use of drugs currently known to cause chemotherapy-related peripheral neuropathy such as platinum (e.g. cisplatin, carboplatin and oxaliplatin), vincristine (e.g. vincristine) and paclitaxel (e.g. paclitaxel and docetaxel), bortezomib and thalidomide. There are no restrictions on tumor type and stage, age, race and sex.

Intervention The experimental group was treated with Huangqi Guizhi Wuwu decoction or Huangqi Guizhi Wuwu decoction combined with positive drugs on the basis of routine chemotherapy. Huangqi Guizhi Wuwu decoction administration method (oral or external washing, fumigation) and dosage form (decoction, granule or capsule) were not limited.

Comparator The control group was given blank control, or placebo control, or positive drug control (duloxetine or mecobalamin) on the basis of routine chemotherapy.There was no significant difference in age, sex, tumor stage, chemotherapy regimen and other baseline data between the control group and the intervention group.

Study designs to be included A randomized controlled clinical trial (RCT) was included to evaluate the efficacy of Huangqi Guizhi Wuwu decoction in the prevention and treatment of peripheral neurotoxicity induced by chemotherapy.

Eligibility criteria Other inclusion criteria: (1) The specific experimental groups that met the intervention measures in the multi-arm RCT of Huangqi Guizhiwuwu decoction combined with other therapies in the prevention and treatment of chemotherapy-induced peripheral neuropathy were extracted (treated with Huangqi Guizhi Wuwu decoction or Huangqi Guizhi Wuwu decoction combined with positive drugs on the basis of routine chemotherapy) and the control group (blank control or placebo control or positive drug control on the basis of routine chemotherapy) were included. (2) Only the study of peripheral neurotoxicity as a safety index was also included in the literature.Exclusion criteria: (1) Ongoing clinical trials, non-randomized controlled trials, uncontrolled case studies, such as reviews, meta-analyses, discussions, conferences, animal or in vitro trials, and other non-clinical trials. (2) The literatures that failed to provide complete outcome data, mismatched outcome indicators or did not describe the scale classification of neurotoxicity. (3) Repeatedly published literature. (4) Those who have been treated with other drugs that may cause neurotoxicity. (5) Subjects with systemic diseases, such as severe cervical spondylosis, severe lumbar intervertebral disc compression, severe diabetes and other non-chemotherapeutic factors. (6) Participants with a history of hand and foot dermatosis and drug allergy. (7) Literature in which the intervention measures of the experimental group were Huangqi Guizhiwuwu decoction combined with other traditional Chinese medicine or traditional Chinese medicine treatment methods (such as acupuncture, acupoint massage, massage, ear point pressure with bean-pressing, etc.).

Information sources PubMed、Embase、Web of Science、Cochrane Central Register of Controlled Trials、China National Knowledge Infrastructure (CNKI)、Wanfang Data(WANFANG)、China Science and Technology Journal Database(VIP) and Chinese BioMedical Literature Database (CBM).

Main outcome(s) The main outcome indicators include Total Incidence of CIPN; Incidence of sever CIPN (level 3 or above). Total effective rates; EORTC QLQ-CIPN20 scale. The neurotoxicity scale was classified by Levi grade, or WHO grade, or NCI grade. Total effective rates: Significant effect: peripheral neurotoxicity grade was 0; Effective: peripheral neurotoxicity grade decreased by more than 1 grade; Ineffective: peripheral neurotoxicity grade had no change or aggravation.

Additional outcome(s) Sensory nerve conduction velocity (median nerve and peroneal nerve), Karnofsky performance score.(KPS) and Adverse events Related to treatment.

Quality assessment / Risk of bias analysis The Cochrane Handbook of Systematic Review of Interventions was used to evaluate the bias risk of included RCTs via the Review Manager5.3 software. The methodological quality of each included literature was assessed through seven aspects, including random method, allocation concealment, blind method. outcome data

integrity, selection report, and other sources of bias, the literature quality was classified into high risk, low risk and unclear risk according to bias of each item.The risk bias is assessed and cross-checked independently by the two researchers, and if there is a disagreement, discuss and decide with the third researcher.

Strategy of data synthesis We use Cochrane RevMan software (version5.3.0) and STATA (version12.0) for data analysis. EORTCQLQ-CIPN20, sensory nerve conduction velocity and KPS score outcome index were continuous variables, which were expressed by average difference (MD) and 95% confidence interval (CI) between test group and control group. Total Incidence of CIPN, Incidence of sever CIPN and Total effective rates outcome indicators are binary variables, expressed as risk ratio (RR), CI is 95%.Heterogeneity was evaluated by I2 statistics and chi-square test. Fixed effect model was used for meta-analysis of low heterogeneity ($P > 0.05$, $I2 \leq 50\%$), while random effect model was used for highheterogeneity (P 50%).

Subgroup analysis Not applicable.

Sensitivity analysis One randomized trial was excluded in turn, and then the rest of the literatures were analyzed and merged with meta. By observing the changes of the merger results, we evaluated whether the original meta analysis results changed significantly under the influence of some studies.

Language restriction No language restrictions are set.

Country(ies) involved China.

Keywords Chemotherapy-Induced Peripheral Neuropathy;Chemotherapy induced peripheral neurotoxicity; Huangqi Guizhi Wuwu Decoction; Meta-Analysis.

Contributions of each author

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