INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Acupuncture methods for prevention and treatment of platinum-induced peripheral neurotoxicity (PIPN): protocol for a systematic review and network meta-analysis

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Review question / Objective: **This work aims to evaluate the current evidence for the efficacy and safety of Acupuncture methods for prevention and treatment of platinum-induced peripheral neurotoxicity (PIPN), and provide reliable evidence-based medical evidence for the clinical treatment of PIPN.**
Condition being studied: **As observed with other chemotherapeutic agents, the clinical application of platinum agents is a double-edged sword. Platinum-induced peripheral neuropathy (PIPN) is a common adverse event that negatively affects clinical outcomes and patients' quality of life. Considering the unavailability of effective established agents for preventing or treating PIPN and the increasing population of cancer survivors, the identification and development of novel, effective interventions is the need of the hour. Although multiple clinical trials and systematic reviews have suggested that acupuncture could be effective in treating PIPN, the comparative efficacy and safety of these acupuncture methods remains unclear. We, therefore, performed this study to evaluate and rank the efficacy and safety of different acupuncture methods for PIPN.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 November 2021 and was last updated on 02 November 2021 (registration number INPLASY2021110003).

INTRODUCTION

Review question / Objective: **This work aims to evaluate the current evidence for the efficacy and safety of Acupuncture methods for prevention and treatment of platinum-induced peripheral neurotoxicity (PIPN), and provide reliable evidence-based medical evidence for the clinical treatment of PIPN.**

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METHODS

Participant or population: The population included patients diagnosed with platinum-induced peripheral neurotoxicity, regardless of gender, age, race, nationality, and other characteristics.

Intervention: We will define acupuncture in this review as acupoint- based therapy, regardless of needling techniques and stimulation method, including manual acupuncture, electro- acupuncture, auricular (ear) acupuncture, acupressure, acupoint application, moxibustion, catgut embedding, transcutaneous electrical acupoint stimulation, acupoint injection and others. We will rule out interventions without stimulating the acupoint.

Comparator: Treatments in the comparison groups can be sham- acupuncture, placebo, pharmacotherapy such as duloxetine or no additional intervention to usual care.

Study designs to be included: Nine databases will be searched, including PubMed, Web of Science, the Cochrane Controlled Trials Central Register System (CENTRAL) Cochrane Library, EMBASE, CNKI, Wanfang Database, Chinese Scientific Journal Database, and Chinese Biomedical Literature database (CBM) from their inception to November 2021. The primary outcome is the change of pain intensity and quality of life. Bayesian network meta- analysis will be conducted using software R3.5.1. Finally, we will use the Grading of Recommendations Assessment, Development and Evaluation System (GRADE) to assess the quality of evidence.

Eligibility criteria: Inclusion criteria:1.The population included patients diagnosed with platinum-induced peripheral neurotoxicity, regardless of gender, age, race, nationality, and other characteristics; 2.We will define acupuncture in this review as acupoint- based therapy, regardless of needling techniques and stimulation method, including manual acupuncture, electro- acupuncture, auricular (ear) acupuncture, acupressure, acupoint application, moxibustion, catgut embedding, transcutaneous electrical acupoint stimulation, acupoint injection and others. We will rule out interventions without stimulating the acupoint. 3. Treatments in the comparison groups can be sham- acupuncture, placebo, pharmacotherapy such as duloxetine or no additional intervention to usual care.The exclusion criteria were as follows: 1. non-randomized controlled trial, and self-control, 2. case report, 3. experience summary, 4. animal experiment research, 5. systematic review, and meta-analysis.

Information sources: We will use the computer to search the following electronic bibliographic databases: PubMed, Web of Science, the Cochrane Controlled Trials Central Register System (CENTRAL) Cochrane Library, EMBASE, China National Knowledge Infrastructure (CNKI), Wanfang Database, Chinese Scientific Journal Database (VIP database), and Chinese Biomedical Literature database (CBM).

Main outcome(s): Quality of life measured by validated scales including the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC- QLQC30), the General Version of the Functional Assessment of Cancer Therapy (FACT- G), the Edmonton Symptom

Assessment System (ESAS) ;The change of pain intensity will be measured by a visual analogue scale (VAS), McGill Pain Questionnaire (MPQ), Brief Pain Inventory (BPI) or other validated outcome measures.

Quality assessment / Risk of bias analysis: Risk of bias in the included studies will be assessed by the Cochrane Risk of Bias Tool according to the Cochrane Handbook 5.1.0 for Systematic Reviews of Interventions, which consists of 7 items of bias relevant to the quality of RCTs. The criteria to be assessed include the following domains: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other bias. An assessment of risk of bias will be made for the included studies based on the following 3 levels:"low risk of bias,""unclear risk of bias," "high risk of bias." Such an evaluation process will be independently performed by 2 researchers, and when differences arise, a third person will be required to participate in the discussion to determine the risk of bias.

Strategy of data synthesis: The 2 reviewers will independently select the literature and extract the data according to the established retrieval strategy, and discuss or consult the third reviewer to make a decision in case of disagreement. During the selection and identification of studies, the 2 reviewers first read the title and abstract of each literature, excluding unrelated studies. The second step is to read the full text of the literature initially identified for inclusion. During the data extraction, the Microsoft Excel data extraction form will be used to extract the data from the literature included.

Subgroup analysis: If the included evidence is rich, we will conduct a subgroup analysis of the factors that influence the outcome, such as: disease types of PIPN and whether accompanied by underlying disease.

Sensitivity analysis: Considering that the diversity of included studies will lead to a certain degree of heterogeneity and inconsistency, we will conduct a sensitivity analysis. This process will be carried out by eliminating each included study. If the heterogeneity does not change after excluding each literature, we think our conclusion is stable; otherwise, if the heterogeneity changes, the excluded literature may be the source of heterogeneity.

Country(ies) involved: China.

Keywords: acupuncture methods; platinum agents; peripheral neurotoxicity; protocol; systematic review.

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