INPLASY PROTOCOL

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Acupuncture therapy for Radiotherapy-induced adverse effects : A protocol for systematic review and Bayesian network metaanalysis

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Review question / Objective: Based on enough clinical researches, we hope to make a systematic review and Bayesian network meta-analysis to evaluate different acupuncture therapeutic effectiveness in treating radiation-induced adverse effects.

Condition being studied: Radiotherapy is a frequent treatment for cancer patients, but without a doubt, its adverse effects are tricky situations. There are common systemic adverse effects such as the decrease of immunological function, myelosuppression, gastrointestinal reactions, in addition to different adverse symptoms and diseases in the light of radiation areas. As widespread complementary and alternative therapies, acupuncture remedies have been proved positive in treating radiotherapy-induced adverse effects.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 July 2020 and was last updated on 14 July 2020 (registration number INPLASY202070054).

INTRODUCTION

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METHODS

Search strategy: PubMed/Medline, Cochrane library, Web of Science, Clinal/ Ebsco, Embase, China National Knowledge Infrastructure (CNKI), Wanfang Database, VIP Database and China Biology Medicine disc(CBM) will be searched from inception to June 2020. The search strategy will contain both radiotherapy and acupuncture including "radiotherapy", "radiation therapy", "cranial irradiation", "Radiotherapy,Computer-Assisted", "acupuncture", "electroacupuncture", "acupuncture therapy" and so on. The search strategy of different databases will be modified properly.

Participant or population: Patients over 18 suffering from radiotherapy-induced adverse effects and radiotherapy simply will be included.

Intervention: Acupuncture therapies are employed as interventions. For example, r e m e d i e s l i k e a c u p u n c t u r e, electroacupuncture, moxibustion, catgut embedding, neuromuscular electrical stimulation are all included. Acupuncture therapy combined with usual care, medicine, enteroclysis will also be taken into consideration.

Comparator: Placebo and usual care are employed as comparisons. Placebo refers to sham acupuncture in most cases while usual care means no extra intervention. Besides, different adverse events may employ revelant medicine and common treatments as interventions of control groups, which is a rational study design thus such circumstances should be accepted. And complementary therapies like cupping therapy and aromatherapy will be excluded.

Study designs to be included: Only peerreviewed randomized control trails(RCTs) can be included.

Eligibility criteria: The eligibility criteria will be achieved when all literatures meet the following requirments. Patients who suffered from adverse reactions induced by radiotherapy as well as radiotherapy simply will be included. Acupuncture therapies are employed as interventions while placebo and usual care are employed as comparisons. Only peer-reviewed randomized control trails(RCTs) can be included.

Information sources: PubMed/Medline, Cochrane library, Web of Science, Clinal/ Ebsco, Embase, China National Knowledge Infrastructure (CNKI), Wanfang Database, VIP Database and China Biology Medicine disc(CBM) will be the sources of information. If we can't find the full text after a full-scale search, contact with the first author. And no grey literature can be included.

Main outcome(s): Main outcomes vary with adverse effects. Here are 2 examples. Studies about vomiting/nausea caused by radiotherapy regard incidence of vomiting/ nausea in 24h or common gastrointestinal adverse reactions established by The National Cancer Institute as a main outcome. Studies about xerostomia caused by radiotherapy regard degree of improvement(high effectivity, moderate effectivity, low effectivity and no effectivity) as a main outcome. Further modifications may be made in the process of this study.

Additional outcome(s): In studies about vomiting/nausea caused by radiotherapy, incidence of vomiting/nausea in 6h, 12h, 72h can also be regarded as additional outcomes. It depends on various research designs.

Quality assessment / Risk of bias analysis: Cochrane risk-of-bias tool (ROB 2.0) will be used to assess the quality. There are 5 sources of bias including bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome and bias in selection of the reported result. And a final risk of bias can be figured out through above assessments. Two reviewers will evaluate all filtered studies and the third reviewer will make the final decision if controversial.

Strategy of data synthesis: Stata , Addis and OpenBugs will be employed to deal with collected data. Stata 14.0 will be used to solve pairwise meta-analysis, with odds ratio (OR) and 95% confidence interval (CI). Addis will be conducted to make a network meta-analysis. OpenBugs will take charge of Bayesian framework.

Subgroup analysis: If related researches are sufficient, patients undergoing the same radiation dosage can be regrouped in these studies. Therefore, it will bring with a subgroup analysis of acupuncture-related therapies for adverse effects induced by different radiation dosage.

Sensibility analysis: Sensibility analysis will be finished if the number of selected studies meet the criteria.

Language: Languages will be limited to Chinese and English.

Country(ies) involved: China.

Keywords: acupuncture therapy; radiotherapy; adverse effects; network meta-analysis.

Contributions of each author:

Author 1 - Tong Wu. Author 2 - Chengwei Fu. Author 3 - Yiran Deng. Author 4 - Wanping Huang. Author 5 - Yang Jiao.