

INPLASY PROTOCOL

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Conflicts of interest:
None.

Acupuncture for the treatment of radiation-induced xerostomia among patients with cancer: A protocol for a systematic review and meta-analysis

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Review question / Objective: The purpose of this review was to evaluate the curative effect about acupuncture treatment of cancer patients after radiotherapy, and provide more reliable evidence for acupuncture treatment of dry mouth after radiotherapy for cancer patients.

Condition being studied: With the number of cancer patients growing, radiotherapy and chemotherapy have been an indispensable treatment. Unfortunately, there are a lot of side effects after radiotherapy and chemotherapy, One of which is xerostomia that always harasses patients. Although there are many ways of treatment of xerostomia, they have many disadvantages. With the rarely side effects and the good effect, acupuncture has been widely applied to dry mouth after radiotherapy, but it has not been accepted as the standard treatment. Because of acupuncture prescription is mostly different and the sample size of studies is small, We need more high quality meta analysis to provide relatively reliable evidence for treatment of radiation-induced xerostomia.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 April 2020 and was last updated on 30 April 2020 (registration number INPLASY202040211).

INTRODUCTION

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treatment of xerostomia , they have many disadvantages. with the rarely side effects and the good effect, acupuncture has been widely applied to dry mouth after radiotherapy, but it has not been accepted as the standard treatment .Because of acupuncture prescription is mostly different and the sample size of studies is small ,We need more high quality meta analysis to provide relatively reliable evidence for treatment of radiation-induced xerostomia.

METHODS

Participant or population: In order to evaluate the efficacy of acupuncture for radiation-induced xerostomia among patients with cancer, we will include any patients with xerostomia caused by cancer radiotherapy.

Intervention: We will only include invasive acupuncture studies for evaluating the therapeutic effect of acupuncture. Changes : meeting, frequency, duration, doctor's background and details of acupuncture point, depth, duration of stay, number of needles are acceptable. The intervention and control groups can be placebo or routine care groups. Invasive acupuncture is defined as acupuncture with needle penetration of skin. On the contrary, non-invasive acupuncture refers to acupuncture that does not use needles or needles do not penetrate the skin, for example, laser acupuncture. Combined interventions will be allowed, such as Chinese medicine, but they must be balanced between the two groups.

Comparator: A control group, which contained drug, no treatment, placebo.

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

Eligibility criteria: In order to evaluate the efficacy of acupuncture for radiation-induced xerostomia among patients with cancer, we will include any patients with xerostomia caused by cancer radiotherapy. non-radiation related xerostomia and non-cancer will not be include.

Information sources: CENTRAL (the Cochrane Library, latest issue);MEDLINE (via OvidSP) ; Embase (via Embase.com) ; Pubmed(via ncbi.nlm.nih.gov);CNKI(via cnki.net) VIP (via cqvip.com); WANFANG DATA (via wanfangdata.com.cn);The metaRegister of Controlled Clinical Trials (www.controlled-trials.com) and ClinicalTrials.gov (www.clinicaltrials.gov).

Main outcome(s): There are two primary and three secondary outcomes. Primary outcomes: (1) Objective : salivary gland flow rate, salivary gland scintigraphy (SGS), or salivary gland functional magnetic resonance imaging (fMRI); (2) Subjective methods : subjective measures of patients' self-reported scores, such as the visual analogue scale, the dry mouth scale, or quality of life. Secondary outcomes: (1) Patient satisfaction with the treatment. (2) The validity of time. (3) Safety indicators: the incidence of adverse reactions and the proportion of patients with abscission.

Quality assessment / Risk of bias analysis: We will use the approach recommended by Cochrane reviews to assess the risks of bias in studies(Higgins 2011). The six specific domains,such as namely sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and 'other bias' ,will be solved by two-part tool. One or more specific entries will be included in a 'Risk of bias' table for every domain. The first part of the tool is that describing what have happend in the reported study. The second part of the tool will be used to judge the risk of bias for that entry, which is obtained by answering a preassigned question about the correlation between the entry and the study (low risk of bias、 high risk of bias and unclear or unknown risk of bias were respectively described as low、 high and unclear).

Strategy of data synthesis: Only if there are studies of similar comparisons reporting the same outcome measures, we will conduct a meta-analysis. We will combine risk ratios for dichotomous data, and we will combine average difference for

continuous data, using fixed-effect models. If there are more than three studies included in any meta-analysis, we will use random-effects models.

Subgroup analysis: We plan to explore clinical heterogeneity by examining the outcome of remission of xerostomia after acupuncture treatment. If sufficient research of each intervention and outcome have been conducted, we will plan to undertake a preliminary subgroup analysis of the different outcomes of the remission of dry mouth.

Sensibility analysis: Sensitivity analysis based on the overall risk of bias will be undertaken, if there have been sufficient research for each outcome and intervention.

Language: No language restrictions.

Country(ies) involved: China.

Keywords: Acupuncture; radiation; xerostomia; cancer; effectiveness; protocol; systematic review.

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