INPLASY PROTOCOL

To cite: Wang et al. The effects of Hangeshashinto for preventing oral mucositis in patients with cancer treatment: a systematic review and meta-analysis. Inplasy protocol 2020100065. doi: 10.37766/inplasy2020.10.0065

Received: 19 October 2020

Published: 19 October 2020

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Support: **Evidence-based construction.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
The authors declare no conflicts of interest.

The effects of Hangeshashinto for preventing oral mucositis in patients with cancer treatment: a systematic review and meta-analysis

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Review question / Objective: **This review aims to assess whether or not the use of Hangeshashinto during cancer treatment can prevent and relieve oral mucositis. Patients: all patients with cancer who were receiving anti-cancer treatment. Intervention: Treatment of oral mucositis with Hangeshashinto. Comparator: other interventions for oral mucositis, including placebo, saline water, usual care and untreated group. Outcomes: Primary outcomes are data on the reduction of signs and symptoms of oral mucositis.**
Condition being studied: **Oral mucositis is a frequent side effects during anti-cancer treatments, affecting over 75% of high-risk patients, which leads to disruption of cancer therapy and higher medical costs. However, there is still no standard approach for preventing it. This protocol proposes a meta-analysis that aims to assess the efficacy and safety of Hangeshashinto (a traditional Kampo) for preventing oral mucositis in patients receiving cancer-related treatments.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 October 2020 and was last updated on 19 October 2020 (registration number INPLASY2020100065).

INTRODUCTION

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METHODS

Participant or population: Cancer patients receiving chemotherapy and/or radiotherapy, at risk of developing oral mucositis as a side effect of this treatment.

Intervention: Treatment of oral mucositis with Hangeshashinto.

Comparator: Other interventions for oral mucositis, including placebo, saline water, usual care and untreated group.

Study designs to be included: We included randomized controlled trials (RCTs) and retrospective study assessing the effects of Hangeshashinto in patients with oral mucositis caused by chemotherapy, radiotherapy, or targeted therapy. Animal studies, case reports, and commentaries will be excluded.

Eligibility criteria: Types of study: we included randomized controlled trials (RCTs) and retrospective study assessing the effects of Hangeshashinto in patients with oral mucositis caused by chemotherapy, radiotherapy, or targeted therapy. Types of Participants/population: cancer patients receiving chemotherapy and/or radiotherapy, at risk of developing oral mucositis as a side effect of this treatment. Types of Intervention(s): treatment of oral mucositis with Hangeshashinto. Types of Comparator(s): other interventions for oral mucositis, including placebo, saline water, usual care and untreated group.

Information sources: The electronic bibliographic databases will be searched from their inception to October 2020, including: MEDLINE, EMBASE, The Cochrane Library, Citation Information by Nii (CiNii); China National Knowledge Infrastructure Database (CNKI). Articles written in English, Japanese and Chinese were mainly considered for inclusion. Strategy Search (MeshTerms and Keywords).

Main outcome(s): The incidence of severe mucositis, defined as the CTCAE v4.0 mucositis grade≥2 or the WHO mucositis grade II, III and IV, based on specific clinical manifestations.

Quality assessment / Risk of bias analysis: Risk of bias will be assessed by two reviewers independently according to the Cochrane Collaboration Risk of Bias Tool. The quality of evidence and grading of strength of recommendations will be assessed by Grades of Recommendation, Assessment, Development and Evaluation (GRADE).

Strategy of data synthesis: Statistical pooling of data using meta-analysis will be conducted whenever it is possible to combine trials and they are relatively homogeneous in relation to design, interventions and outcomes.

Subgroup analysis: Subgroup analyses will be conducted for: 1) The type of cancer; 2) The type of cancer treatment: chemotherapy only; radiotherapy only; chemoradiotherapy; 3) The manner by which Hangeshashinto has been used: oral Hangeshashinto or mouthwash for topical use.

Sensibility analysis: Sensitivity analysis was conducted by excluding the study that the quality was rated as 'high risk'.

Country(ies) involved: China.

Keywords: oral mucositis; cancer treatment; Hangeshashinto.

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