INPLASY PROTOCOL

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Review Stage at time of this submission: Data analysis.

Conflicts of interest: None declared.

INTRODUCTION

Review question / Objective: The purpose of this study was to compare the efficacy and safety of EA-TCM(external application of traditional Chinese medicine) combined with oral opioids versus oral opioids alone in the treatment of CIBP patients, and the

Efficacy and Safety of External Application of Traditional Chinese Medicine Combined with Oral Opioids for Cancer-induced Bone Pain: A Systematic Review and Meta-analysis

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Review question / Objective: The purpose of this study was to compare the efficacy and safety of EA-TCM(external application of traditional Chinese medicine) combined with oral opioids versus oral opioids alone in the treatment of CIBP patients, and the selected research method was a randomized controlled trial.

Condition being studied: Cancer-induced Bone Pain.

Information sources: Cochrane Central Register, Excerpta Medica Database (EMBASE), PubMed, Chinese National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP), Chinese Biomedical Literature Service System (SinoMed), and WanFang Database

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 August 2021 and was last updated on 02 August 2021 (registration number INPLASY202180004).

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Condition being studied: Cancer-induced Bone Pain.

METHODS

Participant or population: CIBP patients.

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Intervention: External application of traditional Chinese medicine combined with oral opioids.

Comparator: Oral opioids alone.

Study designs to be included: RCT.

Eligibility criteria: The diagnostic criteria for malignant tumor were based on the relevant diagnostic criteria in practical Oncology Internal Medicine, with pathological, cytological or clinical diagnosis of malignant tumor (with primary foci) and the diagnosis of bone metastasis by imaging (X ray, CT, MRI or ECT), and with pain.

Information sources: Cochrane Central Register, Excerpta Medica Database (EMBASE), PubMed, Chinese National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP), Chinese Biomedical Literature Service System (SinoMed), and WanFang Database.

Main outcome(s): Pain relief rate, pain score, quality of life, total opioid dose, analgesic onset time, the frequency of breakthrough pain, nausea, constipation, drowsiness and skin allergy.

Quality assessment / Risk of bias analysis: Cochrane manual.

Strategy of data synthesis: Review Manager Software 5.4.1(Nordic Cochran Center, Copenhagen, Denmark) is utilized to carry out the data analysis of dichotomous and continuous outcomes. Continuous data uses weighted mean difference (WMD) or standardized mean difference (SMD), while dichotomous data utilizes risk ratio (RR), both with 95% confidence intervals (CIs). Heterogeneity of test is evaluated by the inconsistency index (I2) statistics. When the heterogeneity shown by statistical results is not statistically significant (P >0.1 and I2 50%), using random effect model.

Subgroup analysis: No subgroup analysis was performed in this study.

Sensitivity analysis: In Review Manager Software 5.4.1, sensitivity analysis was performed to reflect the sensitivity of one article by the change of effect size after deletion.

Country(ies) involved: China.

Keywords: External application of traditional Chinese medicine; cancer induced bone pain; systematic review; meta-analysis.

Contributions of each author:

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