INPLASY PROTOCOL

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None declared.

External Application of Traditional Chinese Medicine in Combination with Three-Step Analgesic Drug Therapy 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 three-step analgesic drug versus three-step analgesic drug in the treatment of patients with CIBP, and the selected research method was a randomized controlled trial.**
Condition being studied: **Cancer-induced Bone Pain.**
Information sources: **Web of Science, Excerpta Medica Database (EMBASE), PubMed, Scopus, 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).

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 three-step analgesic drug versus three-step analgesic drug in the treatment of patients with CIBP, and the selected research method was a randomized controlled trial.**

Condition being studied: **Cancer-induced Bone Pain.**

METHODS

Participant or population: **CIBP patients.**

Intervention: External application of traditional Chinese medicine combined with three-step analgesic drug.

Comparator: Three-step analgesic drug alone.

Study designs to be included: RCT.

Eligibility criteria: Types of participants Studies of patients with definite primary lesions, and bone metastases confirmed by imaging examination and presenting with symptoms of pain could be enrolled in this review. The study did not place limits on age, gender, or nationality. Types of interventions The composition, source, dosage form, and treatment course of EA-TCM are unlimited. Patients in the treatment group received EA-TCM combined with three-step analgesic drug, while patients in the control group should be treated by three-step analgesic drug alone. Types of outcome measures Included studies had at least one clear assessment of efficacy, such as pain relief rate, NRS score, analgesic onset time, frequency of breakthrough pain, laboratory indicators, or adverse effects. Types of studies Randomized controlled trials (RCTs) which have evaluated the effect of EA-TCM combined with three-step analgesic drug for CIBP were included in this study.

Information sources: Web of Science, Excerpta Medica Database (EMBASE), PubMed, Scopus, 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, NRS score, quality of life, analgesic onset time, the frequency of breakthrough pain, laboratory indicators and Side effects.

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, three-step analgesic drug, cancer-induced bone pain, systematic review, meta-analysis.

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