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INPLASY

A systematic evaluation of the clinical value and safety of Cheezheng pain relieving plasters and similar external use of Chinese patent medicine and Western medicine

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ADMINISTRATIVE INFORMATION

Support - Xizang Qizheng Tibetan Medicine Co., LTD.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 June 2025 and was last updated on 17 June 2025.

INTRODUCTION

Review question / Objective In the context of centralized procurement, obtain the clinical value and safety evidence of the pain-relieving patch compared with similar drugs (Yunnan Baiyao ointment, Tongluo pain-relieving ointment, Tianhe bone healing patch, flurbiprofen gel patch, loxoprofen sodium gel patch) with the same efficacy or indications on the market.

Condition being studied The research results will provide scientific basis for medical insurance decision-making departments, promote the transformation of TCM evaluation from "homogeneous bidding" to "differentiated value recognition", and promote the standardization and international development of TCM clinical evidence system.

METHODS

Participant or population People with pain and disease, primary disease type, age and gender are not limited.

Intervention Cheezheng pain relieving plasters (used alone or in combination with other drugs) for external use.

Comparator Yunnan Baiyao Ointment, Tongluo Qutong Ointment, Tianhe Goutong Plaster, Flurbiprofen Gel Plaster, Loxoprofen Sodium Gel Plaster, Placebo, Blank Plaster, and conventional basic treatment were also included as control intervention measures when Qizheng Xiaotong Plaster was used.

Study designs to be included Randomized or non-randomized clinical controlled trials.

Eligibility criteria Additionally, non-external medications were excluded from the control group. Randomized cross-over trials were excluded if the outcomes at each stage were not reported.

Information sources electronic databases: CNKI(https://www.cnki.net), Wanfang(https://www.wanfangdata.com.cn), SinoMed3.0(https://www.sinomed.ac.cn), VIP(https://qikan.cqvip.com/), ProQuest (ProQuest Social Science Premium Collection, https://www.proquest.com) 、PubMed (https://pubmed.ncbi.nlm.nih.gov), Embase (https://www.embase.com) , Cochrane library(https://www.cochranelibrary.com), Web of Science
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Main outcome(s) Pain-related outcomes included pain relief rate(Defined as "efficient rate"), pain severity (different measurement methods such as VAS, NRS scores, etc.), pain relief time, and number of attacks.

Additional outcome(s) Quality of life, joint swelling score, joint dysfunction score, pharmacoeconomic evaluation; safety outcomes: adverse reactions, adverse events.

Quality assessment / Risk of bias analysis Two researchers evaluated the quality of the literature using the Cochrane's ROBII tool, a tool for assessing risk of bias. The evaluation covered aspects such as the generation of random sequences, allocation concealment, blinding of participants and implementers, blinding of outcome assessors, completeness of data, selective reporting of results, and other sources of bias. The two researchers assessed the literature for a risk of bias, categorizing it as high, low, or uncertain. In cases of disagreement, a third-party expert would provide a final decision.

Strategy of data synthesis The Meta-analysis was conducted using Review Manager 5.4 software to examine the heterogeneity among studies and assess its sensitivity. For categorical data, relative risk (RR) was used as the statistical measure, while for continuous data, mean difference (MD) was used. The results were analyzed by examining the combined effect sizes and their 95% confidence intervals (CI). The I2 statistic was used to describe the degree of heterogeneity (with a significance level of α=0.05). If I2 is ≤50% and P is ≥0.1, it indicates that the heterogeneity among studies is not significant, and a fixed effects model is used; if I2>50% or P <0.1, it suggests significant heterogeneity among studies, and a random effects model is used.

Subgroup analysis Subgroup analysis based on clinically relevant factors was divided by different disease types or different control medicine categories.

Sensitivity analysis A leave-one-out analysis was conducted by iteratively removing each included study and recalculating the pooled effect size. Subgroup analyses based on clinically relevant factors (e.g., different disease types or different control medicine categories) were extended to sensitivity testing by excluding studies with outlier characteristics.The sensitivity analysis was carried out by removing each article to identify the source of heterogeneity.

Language restriction No language restrictions.

Country(ies) involved China.

Keywords Cheezheng pain relieving plasters, Systematic evaluation, Clinical controlled trial.

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