INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Pharmaceutical preparations of periplaneta Americana for Pressure ulcer: a protocol for a meta-analysis of randomised controlled trials

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Review question / Objective: **The effect of topical KFX on the rate of healing of Pressure ulcer in any caresetting , and what is the best optimal frequency of use were discussed in this meta-analysis of all relevant randomized controlled trials.**
Eligibility criteria: **(1) This study is a randomized controlled trial; (2) Participants had localized Pressure ulcer without topical medication prior to treatment, excluding skin ulcers caused by tumors; (3) The study evaluated an intervention group and a control group, including topical KFX or KFX in combination with other drug treatment or physical treatment in the intervention group and non-KFX in the control group; (4) Specific steps for topical KFX :The medical gauze was soaked with KFX and applied externally to the affected area, and the outer layer was wrapped with sterile gauze; (5) The baseline status before treatment was clear, and the baseline difference was not statistically significant.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 July 2022 and was last updated on 17 July 2022 (registration number INPLASY202270082).

INTRODUCTION

Review question / Objective: **The effect of topical KFX on the rate of healing of Pressure ulcer in any caresetting , and what is the best optimal frequency of use were discussed in this meta-analysis of all relevant randomized controlled trials.**

Condition being studied: **Pressure ulcer, defined as localized damage to the skin and/or underlying tissue, as result of pressure or pressure in combination with shear, often become chronic wounds that are difficult to treat, and pose both significant health risks and financial burdens. The existing treatment has some disadvantages such as high cost and**

complicated operation, and the standardization of treatment in this field urgently needs to find high-quality evidence to support. The study condition include: (1) Study type: RCT; (2) Participants :patients had localized Pressure ulcer without topical medication prior to treatment, excluding skin ulcers caused by tumors; (3)Intervention: topical KFX or KFX in combination with other drug treatment or physical treatment in the intervention group and non-KFX in the control group; (4) Outcome indicators: the primary outcome (the effective rate: complete healing rate plus remarkably effective rate and Improvement rate) , and the secondary outcomes (the improvement of pain; healing time; recurrence rate; incidence of adverse reactions); (5) Specific steps for topical KFX :The medical gauze was soaked with KFX and applied externally to the affected area, and the outer layer was wrapped with sterile gauze; (6) The baseline status before treatment was clear, and the baseline difference was not statistically significant.

METHODS

Search strategy: Two reviewers will independently search the literature published up to July 2022 in major English and Chinese databases with no language restriction, including PubMed, EMBASE, Web of Science (WOS), Cochrane Central Register of Controlled Trials (CENTRAL), China Network Knowledge Infrastructure (CNKI), Chinese Biomedicine (CBM), Chinese Scientific Journals Database (VIP), and WanFang Database. For any relevant ongoing or unpublished trials, we will search the US National Institutes of Health Ongoing Trials Register (http://www.clinicaltrials.gov), the WHO International Clinical Trials Registry Platform (http://www.who.int/trialsearch) and the metaRegister of Controlled Trials (http://www.controlledtrials.com). Conference abstracts will be searched for potentially relevant trials from inception to July 2022 in OpenSIGLE (opensigle.inist.fr).

Participant or population: Participants had localized Pressure ulcer without topical medication prior to treatment, excluding skin ulcers caused by tumors, including all patients in included literature.

Intervention: Topical KFX with or without other therapeutic measures.

Comparator: Other therapeutic measures except topical KFX.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: (1) This study is a randomized controlled trial; (2) Participants had localized Pressure ulcer without topical medication prior to treatment, excluding skin ulcers caused by tumors; (3) The study evaluated an intervention group and a control group, including topical KFX or KFX in combination with other drug treatment or physical treatment in the intervention group and non-KFX in the control group; (4) Specific steps for topical KFX :The medical gauze was soaked with KFX and applied externally to the affected area, and the outer layer was wrapped with sterile gauze; (5) The baseline status before treatment was clear, and the baseline difference was not statistically significant.

Information sources: Our database include PubMed, EMBASE, Web of Science (WOS), Cochrane Central Register of Controlled Trials (CENTRAL), China Network Knowledge Infrastructure (CNKI), Chinese Biomedicine (CBM), Chinese Scientific Journals Database (VIP), and WanFang Database. For any relevant ongoing or unpublished trials, we searched the US National Institutes of Health Ongoing Trials Register (http://www.clinicaltrials.gov), the WHO International Clinical Trials Registry Platform (http://www.who.int/trialsearch) and the metaRegister of Controlled Trials (http://www.controlledtrials.com). Conference abstracts were searched for potentially relevant trials from inception to July 2022 in OpenSIGLE (opensigle.inist.fr).

Main outcome(s): The effective rate: complete healing rate plus remarkably effective rate and Improvement rate.

Additional outcome(s): The improvement of pain; Healing time; Recurrence rate; Incidence of adverse reactions.

Quality assessment / Risk of bias analysis: Two review authors will independently assess risk of bias in the included studies using the revised version of the Cochrane risk of bias tool for randomised trials (RoB 2). The tools covers the following five domains:1) Bias arising from randomization;2)Bias due to deviations from intended interventions;3) Bias due to missing outcome data;4) Bias in measurement of outcome;5) Bias in selection of the reported results. We will score each of these domains as low risk of bias, some concerns, or high risk of bias for each included study and display these data in two summary figures, one a summary of bias for each item across all studies, and the other showing a cross-tabulation of each trial by all risk of bias items. The evaluation results will be agreed upon by all review authors.

Strategy of data synthesis: We will analyze and synthesize the meta-review research problems into quantitative and qualitative data respectively. The synthesis will perform meta-analysis by generating forest maps. The prism shows the aggregating effect of a particular type of study (depending on the covariates of the metaregression). The fixed effect model will be fitted for calculating pooled estimates, 95%CIs and combined p values if the heterogeneity test indicates there is no substantial heterogeneity between studies (I2 <50%). If substantial heterogeneity is indicated by I2 ≥50%, the random-effects model will be performed.

Subgroup analysis: Subgroup analysis will be performed according to primary and secondary objectives to detect possible heterogeneity of outcomes. We will investigate the effects in the following subgroup analysis: Frequency of KFX. In addition, if we detected any significant and significant covariates leading to changes in the intervention effect through meta-analysis, additional subgroup analyses will be performed based on these covariables Sensitivity analysis will be performed to explore the robustness of the primary outcome. To assess the internal validity or treatment adequacy of the studies, we will then use metafor package and leave 1 out function to delete studies with high bias risk, studies with unclear bias risk, and studies with low bias risk.

Sensitivity analysis: When heterogeneity is high in the analysis results, we will conduct sensibility analysis, and will observed the changes of heterogeneity by excluding references article by article, so as to find out the causes of heterogeneity.

Language: None restriction.

Country(ies) involved: China.

Keywords: Pressure ulcer; Kangfuxin; KFX; meta-analysis; review.

Contributions of each author:

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