INPLASY PROTOCOL

To cite: Zhang et al. Effect and safety of Huangqi-Guizhi-Wuwu Decoction and Erxian Decoction in the treatment of frozen shoulder: a protocol for systematic review and meta-analysis. Inplasy protocol 202040070. doi: 10.37766/inplasy2020.4.0070

Received: 13 April 2020

Published: 13 April 2020

Corresponding author:
Chao Jiang

ChaoJiang198001@outlook.com

Author Affiliation:
The Second Affiliated Hospital of Xi'an Medical Un

Support: **TTPHKDHCSH (HKYQ2018-05)**

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

Conflicts of interest: **No.**

Effect and safety of Huangqi-Guizhi-Wuwu Decoction and Erxian Decoction in the treatment of frozen shoulder: a protocol for systematic review and meta-analysis

Zhang, YW[1]; Jiang, C[2]; Li, XH[3]; Li, K[4].

Review question / Objective: **Can Huangqi-Guizhi-Wuwu Decoction (HGWD) combined Erxian Decoction (EXD) effectively treat frozen shoulder (FS)?**
Condition being studied: **Huangqi-Guizhi-Wuwu Decoction; Erxian Decoction; frozen shoulder.**
Information sources: **We will compressively retrieve the following electronic databases of MEDLINE, EMBASE, Cochrane Library, Cumulative Index to Nursing and Allied Health Literature, PsycINFO, Web of Science, Allied and Complementary Medicine Database, Google Scholar, and China National Knowledge Infrastructure. We will collect all electronic database sources from inception of each electronic database up to present without language and publication status limitations. The example of search strategy with details of MEDLINE is built. The similar search strategies will be utilized to the other electronic databases. Additionally, we will also search Google Scholar, conference proceedings, clinical registration websites, and reference lists of associated reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 April 2020 and was last updated on 13 April 2020 (registration number INPLASY202040070).

INTRODUCTION

Review question / Objective: **Can Huangqi-Guizhi-Wuwu Decoction (HGWD) combined Erxian Decoction (EXD) effectively treat frozen shoulder (FS)?**

Condition being studied: **Huangqi-Guizhi-Wuwu Decoction; Erxian Decoction; frozen shoulder.**

Zhang et al. Inplasy protocol 202040070. doi:10.37766/inplasy2020.4.0070 Downloaded from https://inplasy.com/inplasy-2020-4-0070/

METHODS

Participant or population: All adult participants (18 years old or above) who were diagnosed as FS will be considered regardless country, race, and gender.

Intervention: The treatment group will use HGWD and EXD with no limitation of dosage, frequency and treatment period.

Comparator: As for the comparators, they could be any treatments, such as placebo, western medicine. However, patients who received HGWD or EXD or combination of HGWD and EXD, the trials will be rejected.

Study designs to be included: Only randomized controlled trials (RCTs) of HGWD and EXD in the treatment of FS will be included. Language and publication status is not limited.

Eligibility criteria: This study will include RCTs that compared the HGWD and EXD with other managements for the treatment of FS.

Information sources: We will compressively retrieve the following electronic databases of MEDLINE, EMBASE, Cochrane Library, Cumulative Index to Nursing and Allied Health Literature, PsycINFO, Web of Science, Allied and Complementary Medicine Database, Google Scholar, and China National Knowledge Infrastructure. We will collect all electronic database sources from inception of each electronic database up to present without language and publication status limitations. The example of search strategy with details of MEDLINE is built. The similar search strategies will be utilized to the other electronic databases. Additionally, we will also search Google Scholar, conference proceedings, clinical registration websites, and reference lists of associated reviews.

Main outcome(s): Primary outcome is shoulder pain intensity, as measured by using any validated pain scales.

Additional outcome(s): Secondary outcomes are shoulder function, as checked by using any validated disability Indexes; quality of life, as evaluated by using any validated related scores; and any expected or unexpected adverse events.

Data management: Two qualified evaluators will independently extract data from the selected trials. Any different views between two evaluators will be solved by a third evaluator through discussion. The extracted date mainly includes general study and patient information, such as country, year of publication, first author; study setting; study design; sample size; interventions and controls; outcomes; adverse events; and any other essential data.

Quality assessment / Risk of bias analysis: Two evaluators will independently evaluate study quality for each eligible trial utilizing Cochrane risk of bias tool. This tool covers 7 aspects, and each one is graded as high, unclear and low risk of bias. Any divergences will be worked out by a third evaluator through discussion.

Strategy of data synthesis: In this study, RevMan 5.3 software will be performed to analyze outcome data and to carry out meta-analysis. All continuous data are calculated as mean difference or standardized mean difference and 95% confidence intervals (CIs), while all dichotomous data will be presented as risk ratio and 95% CIs. The I^2 statistics will be used to check statistical heterogeneity across included trials. A value of $I^2 \leq 50\%$ is considered as having homogeneous and data will be pooled using a fixed-effect model. If over two eligible trials are included, a meta-analysis will be planed to be conducted. On the other hand, a value of $I^2 > 50\%$ indicating significant heterogeneity, and data will be synthesized using a random-effect model. We will investigate the reasons for the existence of substantial heterogeneity from several aspects, such as characteristics of study or patient, interventions. The sources of heterogeneity will be further examined using sensitivity analysis.

Zhang et al. Inplasy protocol 202040070. doi:10.37766/inplasy2020.4.0070 Downloaded from https://inplasy.com/inplasy-2020-4-0070/

Subgroup analysis: Subgroup analysis will be addressed to check the potential heterogeneity and inconsistency based on the different study or participant characteristics, treatments, controls, and outcome measurements.

Sensibility analysis: Sensitivity analysis will be investigated to identify the robustness and stability of study results by removing low quality trials.

Country(ies) involved: China.

Keywords: Huangqi-Guizhi-Wuwu Decoction; Erxian Decoction; frozen shoulder; randomized controlled trial; effect; safety.

Zhang et al. Inplasy protocol 202040070. doi:10.37766/inplasy2020.4.0070 Downloaded from https://inplasy.com/inplasy-2020-4-0070/