

INPLASY PROTOCOL

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None declared.

Chinese patent medicine for functional dyspepsia effects: a protocol for systematic review and Bayesian network meta-analysis

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Review question / Objective: P: functional dyspepsia; I: 9 kinds of Chinese patent medicines included: Zhizhu Kuanzhong capsule, Qi-zhi-wei-tong granule, Wei-chang-an pill, Biling Weitong Granules, Si-mo-tang oral liquid, Dalitong granule, Liuwei Anxiao capsule, Liuwei Nengxiao capsule, Huoxiang Zhengqi capsule/pill; C: placebo or western medicine (Domperidone or trimebutin or itobili or moxabili or omeprazole); O: effective rate, cure rate, recurrence rate, symptom score, and adverse events; S: Systematic evaluation and Network Meta-analysis of clinical randomized controlled trials.

Condition being studied: Functional dyspepsia (FD) is one of the most common diseases in gastroenterology outpatient, and its prevalence can be as high as 10%-30%, which is a worldwide public health problem. In recent years, many clinical studies have suggested that various Chinese patent medicines seem to be potential in treating FD, this study aims to make a systematic review and Bayesian network meta-analysis (NMA) to evaluate the effectiveness of various Chinese patent medicine for FD.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 October 2021 and was last updated on 17 October 2021 (registration number INPLASY2021100057).

INTRODUCTION

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METHODS

Search strategy: A comprehensive search will be carried out in the PubMed, Embase, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Database, VIP Database and Wanfang Database, from inception to October 2021. Search terms include functional dyspepsia, name of different Chinese patent medicines, and their synonyms. The search strategy of each database will be modified properly.

Participant or population: For patients diagnosed with FD, the diagnostic criteria include Rome II, Rome III, and Rome IV.

Intervention: 9 kinds of Chinese patent medicines included: Zhizhu Kuanzhong capsule, Qi-zhi-wei-tong granule, Wei-chang-an pill, Biling Weitong Granules, Simo-tang oral liquid, Dalitong granule, Liuwei Anxiao capsule, Liuwei Nengxiao capsule, Huoxiang Zhengqi capsule/pill.

Comparator: Placebo or western medicine (Domperidone or trimebutin or itobili or moxabili or omeprazole). The dosage and course of treatment were unlimited.

Study designs to be included: RCTs based on different Chinese patent medicine for functional dyspepsia, the language is limited to Chinese and English.

Eligibility criteria: 1. Patients with a definite diagnosis of functional dyspepsia. 2. Clinical randomized controlled trials. 3. Intervention: 9 kinds of Chinese patent medicines included: Zhizhu Kuanzhong capsule, Qi-zhi-wei-tong granule, Wei-chang-an pill, Biling Weitong Granules, Simo-tang oral liquid, Dalitong granule, Liuwei Anxiao capsule, Liuwei Nengxiao capsule, Huoxiang Zhengqi capsule/pill. 4. comparator: placebo or western medicine (Domperidone or trimebutin or itobili or moxabili or omeprazole).

Information sources: Searches were conducted on 8 electronic databases: PubMed, Web of Science, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI), China Biology Medicine disc (CBM), VIP Database, and Wanfang Database.

Main outcome(s): The main outcomes will be total clinical efficiency, cure rate, recurrence rate, symptom score, and adverse events.

Quality assessment / Risk of bias analysis: Cochrane risk-of-bias tool will be carried to assess the quality of RCTs.

Strategy of data synthesis: Pairwise meta-analysis - For dichotomous variables, odds ratio (OR) and 95% confidence intervals (CI) will be adopted, while for continuous variables, outcomes will be expressed as standard mean difference, and 95% CI.² test will be used to assess heterogeneity. Network meta-analysis - The Markov chain Monte Carlo method will be used to combines both direct and indirect evidence. And density plots, Brooks-Gelman-Rubin diagnosis plots, and trace plots were adopted to assess model convergence.

Subgroup analysis: We will perform subgroup analysis if the heterogeneity is high ($I^2 > 50\%$).

Sensitivity analysis: Sensitivity analysis will be taken by changing the effect model or removing 1 study at a time to investigate

the influence of a single study on the overall pooled estimate.

Country(ies) involved: China.

Keywords: Network meta-analysis (NMA); Functional dyspepsia (FD); Chinese patent medicine; traditional Chinese medicine (TCM).

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