# INPLASY PROTOCOL

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## Systematic evaluation and Metaanalysis of Three Seeds Decoction in the treatment of functional dyspepsia compared with cisapride and mosapride

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Review question / Objective: P:functional dyspepsia; I:Three seeds decoction; C:Mosapride or Cisapride; O:total clinical efficiency, gastric emptying rate, recurrence rate, gastroprokinetic hormone, gastrin, abdominal distention, belching, nausea and vomiting, early satiety, gastric fullness, dullness, loose stools, bitter or sticky mouth, and limb sleepiness; S:Systematic evaluation and Meta-analysis of clinical randomized controlled trials.

Condition being studied: Many clinical studies have concluded that Three seeds decoction is more effective than Cisapride and Mosapride in the treatment of functional dyspepsia, but there are no evidence-based medical studies on the difference in efficacy of Three Seeds Decoction against Cisapride and Mosapride in the treatment of FD.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 June 2021 and was last updated on 23 June 2021 (registration number INPLASY202160084).

## **INTRODUCTION**

Review question / Objective: P:functional dyspepsia; I:Three seeds decoction; C:Mosapride or Cisapride; O:total clinical efficiency, gastric emptying rate, recurrence rate, gastroprokinetic hormone, gastrin, abdominal distention, belching, nausea and vomiting, early satiety, gastric

fullness, dullness, loose stools, bitter or sticky mouth, and limb sleepiness; S:Systematic evaluation and Meta-analysis of clinical randomized controlled trials.

Condition being studied: Many clinical studies have concluded that Three seeds decoction is more effective than Cisapride and Mosapride in the treatment of

functional dyspepsia, but there are no evidence-based medical studies on the difference in efficacy of Three Seeds Decoction against Cisapride and Mosapride in the treatment of FD.

#### **METHODS**

Search strategy: The search period is from January 1, 1949 to January 31, 2021. Search strategy for Pubmed: (((((("sanren tang"[Title/Abstract]) OR ("three seeds decoction"[Title/Abstract])) OR ("sanrentang"[Title/Abstract])) OR ("decoction of three seeds"[Title/ Abstract])) OR ("three nut decoction"[Title/ Abstract])) OR ("sanren decoction"[Title/ Abstract])) OR ("three kernel soup"[Title/ Abstract])) AND ((((("functional dyspepsia"[Title/Abstract]) OR (dyspepsia[Title/Abstract])) OR (dyspepsias[Title/Abstract])) OR (indigestion[Title/Abstract])) OR (indigestions[Title/Abstract])) OR (FD[Title/ Abstract])) . The search strategy for the China National Knowledge Infrastructure was: "Three seeds decoction" and "dyspepsia".

Participant or population: Patients with a confirmed diagnosis of functional dyspepsia. No requirement for gender or age.

Intervention: The intervention for the observation group was the traditional Chinese medicine formula Three seeds decoction.

Comparator: The intervention in the control group was Mosapride or Cisapride.

Study designs to be included: Inclusion criteria: 1) Studies with a definite diagnosis of functional dyspepsia. 2) Clinical randomized controlled trials. 3) Intervention in the treatment group was Three seeds decoction. 4) Intervention in the control group was Mosapride or Cisapride.

Eligibility criteria: 'Rome III Criteria for Functional Dyspepsia' and the 'Guidelines for Clinical Research on New Chinese Medicines'.

Information sources: Searches were conducted on 7 electronic databases and 2 paper databases, including PubMed, EMbase, Cochrane library, China National Knowledge Infrastructure(CNKI), Wanfang database, VIP Journal Resource Integration Service Platform(VIP), China Biomedical Database, the Library of Hebei Provincial and the Library of Hebei university of Chinese Medicine.

Main outcome(s): This study includes the following 14 indicators,1)total clinical efficiency rate, 2).gastric emptying rate, 3).recurrence rate, 4).molitin, 5).gastrin, 6).abdominal distention, 7).belching, 8).nausea and vomiting, 9).early satiety, 10). fullness in stomach, 11).anorexia, 12).loose stools, 13).bitter taste or sticky in mouth, 14).body trapped. At the same time, the risk of bias, heterogeneity, sensitivity, and publication bias was also analyzed for each part of the study. Risk of bias analysis, heterogeneity, sensitivity analysis, and publication bias analysis for each part of the study were also included.

Data management: Using NoteExpress A for literature management and Review manager for data analysis.

Quality assessment / Risk of bias analysis: Evaluation of included studies using the Chochrane Risk of Bias Assessment Tool.

Strategy of data synthesis: Dichotomous variables such as total clinical efficacy rate, gastric emptying rate, and recurrence rate were analyzed by using the Risk Ratio(RR). Continuous variables such as motilin, gastrin, abdominal distension, belching, nausea and vomiting, early satiety, fullness in the stomach, anorexia, loose stools, bitter taste or sticky in the mouth, and body trapped were analyzed by mean difference (MD).

Subgroup analysis: In case of high heterogeneity, the source of heterogeneity should be analyzed and the heterogeneity of the study should be reduced utilizing subgroup analysis. According to the different interventions in the control group, they were divided into 2 subgroups of

Three seeds decoction verse Mosapride and Three seeds decoction verse Cisapride.

Sensitivity analysis: The stability of the study results was judged by observing whether there was a significant change in the results after excluding each study in turn and changing the chosen model. If studies with a large impact on the results were found, they should be excluded.

Language: No limits.

Country(ies) involved: China.

Keywords: Functional Dyspepsia; systematic review; Meta-analysis; three seeds decoction; mosapride; cisapride.

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