# INPLASY PROTOCOL

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Conflicts of interest: None declared.

# Systematic Review and Meta-analysis of Sanren Decoction and Domperidone in the treatment of Functional Dyspepsia

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Review question / Objective: P: functional dyspepsia; I: Three seeds decoction; C: Domperidone; O: total clinical efficiency, relapse rate, Motilin, gastrin, Belching, Bloating, Early satiety, epigastric pain in the patients of functional dyspepsia; S: Systematic evaluation and Meta-analysis of clinical randomized controlled trials.

Condition being studied: Functional dyspepsia severely affects the quality of patients' life. Its prevalence is about 18% to 45%, with a long duration of illness, recurrent symptoms. Mosapride and Cisapride are the empirical therapeutic agents of choice for the treatment of Functional dyspepsia(FD). The Chinese herbal formula Three Seeds Decoction is outstandingly effective in the treatment of FD. 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. We plan to evaluate the difference in efficacy of three seeds decoction versus Mosapride and Cisapride by analyzing the improvement in total clinical efficiency rate, gastric emptying rate, recurrence rate, molitin, gastrin, abdominal distention, belching, nausea and vomiting, early satiety and so on.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 September 2021 and was last updated on 24 September 2021 (registration number INPLASY202190084).

# **INTRODUCTION**

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#### **METHODS**

Search strategy: ((((((("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])) OR ("three kernel soup"[Title/Abstract])) OR ((((("functional dyspepsia"[Title/Abstract])) OR (dyspepsia [Title/Abstract])) OR (indigestion [Title/Abstract])) OR (indigestions [Title/Abstract])) OR (FD[Title/Abstract])).

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

Intervention: Sanren decoction for Observation group.

Comparator: Domperidone for Control group.

Study designs to be included: Randomized controlled trials only.

Eligibility criteria: 1.Rome III Criteria for FD 2.Diagnosis and Treatment Protocols of FD

with Integrative Chinese and Western Medicine

Information sources: Search of PubMed, EMbase, Cochrane library, Web of science, CNKI, Wanfang database, VIP database, and Chinese biomedical literature databases for clinical randomized controlled studies on functional dyspepsia between 1949 and 2021.

Main outcome(s): Total clinical efficiency, recurrence rate, promotion of gastrin secretion, symptom score of abdominal distension and epigastric pain.

Data management: Review manager 5.3& Excel.

Quality assessment / Risk of bias analysis: Cochrane Risk of Bias Assessment Tool.

Strategy of data synthesis: For binary variables such as total clinical efficacy rate, gastric emptying rate, and recurrence rate use risk ratio (RR) for analysis. For continuous variables such as motilin, gastrin, abdominal distension, belching, nausea and vomiting, early satiety, gastric and epigastric fullness, anorexia, loose stools, bitter taste or sticky in mouth, and somnolence and fatigue were analyzed by using mean difference (MD).

Subgroup analysis: Subgroups according to interventions.

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; sanren decoction; Domperidone; systematic review; Meta analysis.

## Contributions of each author:

Author 1 - Hui Gao - In the retrieval, evaluation and production of this paper.

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Author 2 - Jingyao Zhang - In the retrieval, evaluation and production of this paper.

Author 3 - Xi Wang - Working for deta checking and embellishment.

Author 4 - Xue Han - Working for deta checking and embellishment.

Author 5 - Yu Liu - Working for deta extracting and embellishment.

Author 6 - Chenxu Liu - Working for deta checking and embellishment.

Author 7 - Aiyangzi Lu - Data Analysis & Proofreading.

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