INPLASY PROTOCOL

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None declared.

Efficacy of Li-Zhong Decoction in the treatment of patients with functional dyspepsia: A protocol for systematic review and meta-analysis

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Review question / Objective: **To evaluate the safety and efficacy of LZD in the treatment of FD. In this study, all theory is adopted the soup randomized controlled trials for the treatment of functional dyspepsia.**
Condition being studied: **Although the disease is not life-threatening, it can take a psychological and financial toll on sufferers. At present, the efficacy of conventional treatment is not significant. Previous studies have shown that Lizhong decoction is safe and effective, but there is a lack of systematic evaluation. The purpose of this study was to systematically study the efficacy of LZD in the treatment of FD patients.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 April 2022 and was last updated on 06 April 2022 (registration number INPLASY202240029).

INTRODUCTION

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METHODS

Participant or population: Systematic review will consider FD patients according to relevant guidelines or consensus. Diagnostic criteria for the trial of FD Roman IV standard, including postprandial abdominal distension, early satiety, abdominal pain, burning sensation in the upper abdomen. Serious cardiac insufficiency, severe hepatic insufficiency, severe renal insufficiency, endocrine disease, cholecystitis, pancreatitis, pepticulcer, etc are not included in other types of diseases. The patient's gender, age, race and area we will be treated fairly.

Intervention: The evaluation included studies of interventions using LZD alone or in combination with other conventional drug therapies. Used in oral medicine, dosage form for liquid or particles. The control group given routine drug or placebo treatment.

Comparator: The control group received conventional medication or placebo treatment.

Study designs to be included: A systematic review and meta-analysis of existing clinical studies was conducted to demonstrate the efficacy of LZD in the treatment of functional dyspepsia. Eight databases were used for literature retrieval and strict standards were followed. Inclusion and exclusion criteria have been previously discussed without dispute.

Eligibility criteria: 1.Patients with a definite diagnosis of functional dyspepsia. 2. Clinical randomized controlled trials. 3. Interventionin: using LZD alone or in combination with other conventional drug therapies LZD. 4. comparator: placebo or western medicine.

Information sources: We will search the database: PubMed, EMBASE, Web of Science, Central, Chinese databases China Biomedical Literature (CBM), Wanfang Chinese digital periodical and conference database (Wanfang Database), China National Knowledge Infrastructure database (CNKI), and VIP Chinese Science and Technique Journals Database (VIP) from inception to February 2022. For the paper, randomized controlled trials (RCT) related to LZD therapy of FD will be selected. In the National Institutes of Health (NIH) clinical registry platform, International Clinical Trial Register Platform (ICTRP) and Chinese clinical trial register platform retrieval or not published clinical trials are ongoing.

Main outcome(s): The total clinical response rate will be used as a primary measure of the drug's effectiveness. Secondary results including anxiety self-assessment scale, depression self rating scale, functional dyspepsia symptom scores, indigestion related symptom scores, relapse after treatment, and adverse events.

Data management: When two researchers have different opinions, discuss them with a third researcher. We show a specific screening process based on the PRISMA flow diagram.

Quality assessment / Risk of bias analysis: The quality of the included literature will be graded according to seven parameters published in the Cochrane Manual and correctly evaluated by two researchers. If there is disagreement during the assessment process, discuss with a third party to assess the risk of bias.

Strategy of data synthesis: RevMan version 5.4 will be used to conduct a meta-analysis to arrive at important conclusions regarding the clinical effects of LZD. Based on the analysis results, we will utilize the relative risk and 95% confidence interval, to evaluate the results of binary classification, while the use of standardized mean difference and 95% confidence interval, to assess the continuous variables.Heterogeneity will be assessed using I2 values (Higgins I-square test).

Subgroup analysis: We will perform subgroup analysis if the heterogeneity is high(I2 >50%).

Sensitivity analysis: A funnel plot analysis will be drawn to assess the occurrence of bias and a Egger test will be performed in Stata 14.0 (Stata Corp, College Station, TX) for statistical investigation.

Language: Chinese and English.

Country(ies) involved: China.

Keywords: functional dyspepsia, systematic review, herbal medicine, lizhong decoction.

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