

INPLASY PROTOCOL

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None declared.

Effectiveness and safety of traditional Chinese medicine enema for treating severe acute pancreatitis

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Review question / Objective: P: Patients with severe acute pancreatitis; I: treat with traditional Chinese medicine enema; C: Treat without traditional Chinese medicine enema; O: Primary outcome measures in our study is all-cause death, and secondary outcome measures include admission to the intensive care unit (AICU), requirement for mechanical ventilation (MV), persistent organ failure (POF) and formation of pancreatic pseudocyst; S: RCT

Condition being studied: Traditional Chinese medicine enema is a traditional way to treat severe acute pancreatitis (SAP) in China. However, there is no systematic reviews for the evidence and the therapeutic effectiveness and safety of traditional Chinese medicine enema for treating SAP. The aim of this study is to summarize previous evidence, assessing the efficacy and safety of traditional Chinese medicine enema in the treatment of SAP.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 May 2022 and was last updated on 29 May 2022 (registration number INPLASY202250163).

INTRODUCTION

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METHODS

Participant or population: Age ≥ 18 years old, a minimum hospital stay of 24h and diagnosis of severe acute pancreatitis.

Intervention: Treat with traditional Chinese medicine enema.

Comparator: Treat without traditional Chinese medicine enema.

Study designs to be included: RCT.

Eligibility criteria: The inclusion criteria for the study will include: 1. studies with patient age ≥ 18 years old, a minimum hospital stay of 24h and a diagnosis of SAP; 2. conference abstracts were only included when they provided adequate relevant information for assessment; 3. the patients with SAP were divided into two groups (treated with traditional Chinese medicine enema or not).

Information sources: We will search the CNKI, PubMed, EMBASE, WANFANG DATA, Web of Knowledge, Cochrane Library and ClinicalTrials.gov from inception to December 30, 2022 to retrieve relevant studies using the search strategy: ("traditional Chinese medicine enema" OR "Herbal enema") AND ("pancreatitis" OR "pancreatitides"). No language restrictions will be applied. We will also search citations of relevant primary and review. Authors of abstract in the meeting will be

further searched in PubMed for potential full articles. To minimize the risk of publication bias, we will conduct a comprehensive search that included strategies to find published and unpublished studies.

Main outcome(s): Primary outcome measures in our study is all-cause mortality.

Additional outcome(s): Admission to the intensive care unit (AICU), requirement for mechanical ventilation (MV), persistent organ failure (POF) and formation of pancreatic pseudocyst.

Quality assessment / Risk of bias analysis: Risk of bias assessment will be carried out according to the Newcastle–Ottawa Scale (NOS) to rate the internal validity of the individual studies, and funnel plots will be constructed to assess the risk of publication bias.

Strategy of data synthesis: All pairwise meta-analytic calculations will be performed with Review Manager software (RevMan) version 5.3 (Cochrane Collaboration). Heterogeneity will be examined by computing the Q statistic and I² statistic, and presence of reporting bias by visual inspection of funnel plots. Statistical significance was considered when the P value < 0.05 .

Subgroup analysis: Patients with severe acute pancreatitis treated with traditional Chinese medicine enema.

Sensitivity analysis: Heterogeneity will be examined by computing the Q statistic and I² statistic, and presence of reporting bias by visual inspection of funnel plots. Statistical significance was considered when the P value < 0.05 .

Country(ies) involved: China.

Keywords: severe acute pancreatitis, traditional Chinese medicine enema, meta-analysis, systematic review, mortality, prognosis.

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