INPLASY PROTOCOL

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Conflicts of interest:
None declared.

A comparison of the efficacy and safety of complementary and alternative therapies for acute pancreatitis: A protocol for network meta-analysis

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Review question / Objective: **Network meta-analysis of comparison of the efficacy and safety of complementary and alternative therapies for acute pancreatitis.**
Condition being studied: **Acute Pancreatitis (AP) is a commonly encountered acute abdominal inflammatory disorder and it is part of one of the leading causes of hospitalization among gastrointestinal diseases. The incidence of AP is 34 per 100,000 among human beings, and it is rising worldwide. In the United States, acute pancreatitis leads to 270,000 hospital admissions annually, and inpatient costs exceed 2.5 billion dollars. Despite improvements in critical care, the overall mortality rate is about 5% to 10%, but 36% to 50% in patients with severe pancreatitis. Therefore, it is necessary to improve the managements of patients with AP. Many studies and system reviews have confirmed the clinical effect of complementary and alternative therapies for acute pancreatitis. Complementary and alternative therapies that are widely used to treat acute pancreatitis include acupressure, retention of enema with Chinese medicine, et al. The guidelines also show that traditional Chinese medicine can help to promote the recovery of gastrointestinal function in patients with acute pancreatitis, reduce abdominal pain and abdominal distension. There are many complementary and alternative therapies for acute pancreatitis, but there is no study on a comprehensive comparison among them. So, we conducted this network meta-analysis (NMA) protocol to evaluate the efficacy and safety of different complementary and alternative therapies in the treatment of acute pancreatitis, hoping to provide comprehensive evidence.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 July 2022 and was last updated on 28 July 2022 (registration number INPLASY202270119).

INTRODUCTION

Review question / Objective: **Network meta-analysis of comparison of the efficacy and safety of complementary and alternative therapies for acute pancreatitis.**

Condition being studied: Acute Pancreatitis (AP) is a commonly encountered acute abdominal inflammatory disorder and it is part of one of the leading causes of hospitalization among gastrointestinal diseases. The incidence of AP is 34 per 100,000 among human beings, and it is rising worldwide. In the United States, acute pancreatitis leads to 270,000 hospital admissions annually, and inpatient costs exceed 2.5 billion dollars. Despite improvements in critical care, the overall mortality rate is about 5% to 10%, but 36% to 50% in patients with severe pancreatitis. Therefore, it is necessary to improve the managements of patients with AP. Many studies and system reviews have confirmed the clinical effect of complementary and alternative therapies for acute pancreatitis. Complementary and alternative therapies that are widely used to treat acute pancreatitis include acupressure, retention of enema with Chinese medicine, et al. The guidelines also show that traditional Chinese medicine can help to promote the recovery of gastrointestinal function in patients with acute pancreatitis, reduce abdominal pain and abdominal distension. There are many complementary and alternative therapies for acute pancreatitis, but there is no study on a comprehensive comparison among them. So, we conducted this network meta-analysis (NMA) protocol to evaluate the efficacy and safety of different complementary and alternative therapies in the treatment of acute pancreatitis, hoping to provide comprehensive evidence.

METHODS

Participant or population: Patients with a confirmed diagnosis of acute pancreatitis.

Intervention: The experimental group should receive complementary and alternative therapies in combination with or without other treatments.

Comparator: The control group is treated with other drugs recommended in international authorized clinical guidelines, or placebo.

Study designs to be included: We will include randomized controlled trials (RCTs) of TCM for acute pancreatitis published in Chinese or English ,regardless of blinding or allocation concealment.

Eligibility criteria: 1.Type of study: We will include randomized controlled trials (RCTs) of TCM for acute pancreatitis published in Chinese or English ,regardless of blinding or allocation concealment.2.Participants: Patients with a confirmed diagnosis of acute pancreatitis.3.Interventions: The experimental group should receive complementary and alternative therapies in combination with or without other treatments4.Comparators: The control group is treated with other drugs recommended in international authorized clinical guidelines, or placebo.5. Outcome: The primary outcomes: abdominal pain, nausea/vomiting, and length of hospital stay; The secondary outcomes: the level of serum amylase, mortality, adverse reactions.

Information sources: We will search several databases, including PubMed, Embase, Web of Science, Cochrane Library, China National Knowledge Infrastructure (CNKI), Wan Fang Database (Wan Fang), Chinese Biomedical Literature Database (CBM), VIP Database for Chinese Technical Periodicals (VIP), Medline, and Clinical Trial Register (CTR) for eligible RCTs. Published trial will be from their inception to June 2022.

Main outcome(s): The effectiveness rate, abdominal pain, nausea/vomiting, and time to first defecation.

Additional outcome(s): The secondary outcomes: the level of serum amylase, mortality, adverse reactions.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess risk of bias based on the following domains from recommendations from the Cochrane handbook: 1. Adequate sequence generation; 2. Allocation concealment; 3. Blinding; 4. Incomplete outcome data and how it was addressed; 5. Selective

reporting of the outcome; 6. Any other biases. results of bias assessment will be presented in a figure and a graph indicating low, high or unclear risk of bias for each of the 6 items in each trial. Sensitivity analysis will be conducted based on the bias assessment to assess robustness of results.

Strategy of data synthesis: A 2-stage approach to the data synthesis will be used. 1. Pairwise meta-analyses In this process, continuous data will be analyzed by mean difference (MD) or standardized mean difference (SMD). dichotomous data will be analyzed by Odds Ratio (OR), the 95% credible interval (CI) will be calculated. We will also use I2 test to assess statistical heterogeneity. 2. NetworkPairwise meta-analyses We will execute Bayesian network meta-analysis of Markov chain Monte Carlo methods in WinBUGS 1.4.3(MRC Biostatistics Unit, Cambridge, UK). We will adopt random-effects and consistency models, Calculate the area under the cumulative sorting curve with Stata 15 software.

Subgroup analysis: The following factors will be used in subgroup analysis: Degree of disease.

Sensitivity analysis: we will perform sensitivity analysis for the primary outcomes by excluding studies with high risk of bias.

Country(ies) involved: China.

Keywords: complementary and alternative therapies, acute pancreatitis, protocol, network meta-analysis.

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