INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Comparison of acupuncture and pinaverium bromide in the treatment of irritable bowel syndrome：a protocol for systematic review and meta-analysis

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Review question / Objective: **Type of studies: All RCTs which compared acupuncture with pinaverium bromide. RCTs conducted in adults without regional and language restrictions. Type of participants: All patients diagnosed with IBS, regardless the age, sex, source of cases, and IBS type. Diagnosis of IBS based on specific diagnostic criteria (Rome I criteria, Rome II criteria, Rome III criteria, Rome IV criteria or the Manning criteria). Type of interventions: The intervention group is defined as acupuncture treatment, such as electroacupuncture, warm acupuncture, moxibustion, ear acupuncture, fire needling, or elongated needle. The acupoint numbers, retaining time and frequency will not be restricted in this protocol. Type of comparators: The control group that will include Patients with IBS taking pinaverium bromide. Types of outcome measures. Primary outcomes: The primary outcomes assessed will be the total effective rate. Secondary outcomes: Secondary outcome measures include the IBS Symptoms Severity Score (IBS-SSS), the IBS Quality of Life (IBS-QOL), 36-Item Short Form (SF-36) and the rate of adverse effects (AEs).**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 March 2021 and was last updated on 19 March 2021 (registration number INPLASY202130068).

INTRODUCTION

Review question / Objective: **Type of studies: All RCTs which compared acupuncture with pinaverium bromide. RCTs conducted in adults without regional and language restrictions. Type of participants: All patients diagnosed with IBS, regardless the age, sex, source of cases, and IBS type. Diagnosis of IBS based on specific diagnostic criteria (Rome I criteria, Rome II criteria, Rome III criteria, Rome IV criteria or the Manning criteria). Type of interventions: The intervention**

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Condition being studied: Irritable bowel syndrome (IBS) is one of the most common chronic gastrointestinal diseases, and the current diagnosis of IBS is still based on symptoms and examination. Pinaverium bromide is commonly used as an antispasmodic in the treatment of IBS. But adverse effects (AEs) of pinaverium bromide are common. Meta analyses show that acupuncture has a positive therapeutic effect on IBS.

METHODS

Search strategy: ((((((((((Irritable bowel syndrome[MeSH Terms])) OR (Irritable Bowel Syndromes)) OR (Syndrome, Irritable Bowel)) OR (Syndromes, Irritable Bowel)) OR (Colon, Irritable)) OR (Irritable Colon)) OR (Colitis, Mucous)) OR (Colitides, Mucous)) OR (Mucous Colitides)) OR (Mucous Colitis)) AND ((((((((((((((((Acupuncture[MeSH Terms]) OR (Pharmacopuncture)) OR (Acupuncture Therapy)) OR (Electroacupuncture)) OR (Manual Acupuncture)) OR (Dry Needle)) OR ((Moxibustion[MeSH Terms]) OR (moxibustion))) OR (Acupuncture, Ear[MeSH Terms])) OR (acupuncture, Ear)) OR (ear acupuncture)) OR (Auricular Acupuncture)) OR (Ear Acupuncture)) OR (Acupuncture, Auricular)) OR (acupuncture, Auricular)) OR (auricular acupuncture)) OR (Warm Acupuncture)) OR (Fire Needling)) OR (Elongated Needle))) AND (randomized controlled trial[Publication Type] OR randomized[Title/Abstract] OR placebo[Title/Abstract]).

Participant or population: All patients diagnosed with IBS, regardless the age, sex, source of cases, and IBS type. Diagnosis of IBS based on specific diagnostic criteria (Rome I criteria, Rome II criteria, Rome III criteria, Rome IV criteria or the Manning criteria).

Intervention: The intervention group is defined as acupuncture treatment, such as electroacupuncture, warm acupuncture, moxibustion, ear acupuncture, fire needling, or elongated needle. The acupoint numbers, retaining time and frequency will not be restricted in this protocol.

Comparator: The control group that will include Patients with IBS taking pinaverium bromide.

Study designs to be included: All RCTs which compared acupuncture with pinaverium bromide. RCTs conducted in adults without regional and language restrictions.

Eligibility criteria: 1.Type of studies: All RCTs which compared acupuncture with pinaverium bromide. RCTs conducted in adults without regional and language restrictions. 2.Type of participants: All patients diagnosed with IBS, regardless the age, sex, source of cases, and IBS type. Diagnosis of IBS based on specific diagnostic criteria (Rome I criteria, Rome II criteria, Rome III criteria, Rome IV criteria or the Manning criteria). 3.Type of interventions: The intervention group is defined as acupuncture treatment, such as electroacupuncture, warm acupuncture, moxibustion, ear acupuncture, fire needling, or elongated needle. The acupoint numbers, retaining time and frequency will not be restricted in this protocol. 4.Type of comparators: The control group that will include Patients with IBS taking pinaverium bromide. 5.Types of outcome measures. Primary outcomes: The primary outcomes assessed will be the total effective rate. Secondary outcomes:

Secondary outcome measures include the IBS Symptoms Severity Score (IBS-SSS), the IBS Quality of Life (IBS-QOL), 36-Item Short Form (SF-36) and the rate of adverse effects (AEs).

Information sources: RCTs of comparing the efficacy of acupuncture and pinaverium bromide in the treatment of IBS will be searched in the relevant database: PubMed, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI), Wanfang Database, Chinese Biomedical Literature Database (CBM) and Chinese Scientific Journal Database (VIP database).

Main outcome(s): The primary outcomes assessed will be the total effective rate.

Additional outcome(s): Secondary outcome measures include the IBS Symptoms Severity Score (IBS-SSS), the IBS Quality of Life (IBS-QOL), 36-Item Short Form (SF-36) and the rate of adverse effects (AEs).

Data management: Data will be carried out independently from the selected articles by two reviewers using a Microsoft Excel spreadsheet. Information extracted from each included article will include first author, publication year, sample size, characteristics of participants, type of treatments, outcome measures, and adverse events. The causes of both selections will be documented and full texts will be obtained and checked for further evaluation if necessary. We will try to contact corresponding authors for missing data. If the missing data cannot be obtained, we will delete the studies related to the missing data.

Quality assessment / Risk of bias analysis: The risk of bias in the included literature will be assessed according to the Cochrane Collaboration's tool for assessing risk of bias.[24] We will assess the risk of bias from the following seven items: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias. The risk of bias graph and the risk of bias summary will be generated by Review Manager (RevMan) V.5.3 software. Any disagreement should be solved in consultation with a third reviewer.

Strategy of data synthesis: Fixed effects models will be used if the I2 value is <50%. Otherwise, we will remove low-quality studies and use sensitivity analysis to investigate which study has the most significant impact on heterogeneity. If quantitative synthesis is not possible, we will make a qualitative description.

Subgroup analysis: If there is significant heterogeneity between the study results, we will perform a subgroup analysis to investigate differences in gender, age, types of acupuncture interventions styles, etc.

Sensitivity analysis: We will use sensitivity analysis to evaluate the stability of decision-making during the review process. Several factors in the meta-analysis process will be taken into consideration, such as low-quality research, small sample research, etc. In addition, we will give the results of the sensitivity analysis in the summary table. The results of the sensitivity analysis will discuss the risk of bias in the meta-analysis.

Language: Without language restrictions.

Country(ies) involved: China.

Keywords: irritable bowel syndrome, acupuncture, pinaverium bromide, complementary therapy, functional gastrointestinal diseases.

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