INPLASY PROTOCOL

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Corresponding author:
Jiawang Jiang

1137298371@qq.com

Author Affiliation:
Jiangxi University of Traditional Chinese Medicine

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None declared.

Effectiveness of Tong-Xie-Yao-Fang combined with Si-Ni-San for irritable bowel syndrome: A protocol for systematic review and meta-analysis

Jiang, JW[1]; Chen, Y[2]; Hu, ZY[3]; Ye, J[4]; Li, HY[5]; Yu, ZY[6]; Tang, HY[7].

Review question / Objective: **Effectiveness of Tong-Xie-Yao-Fang combined with Si-Ni-San for irritable bowel syndrome.**
Condition being studied: **Irritable bowel syndrome (IBS) has a high morbidity rate worldwide, but there are no effective treatment measures, which seriously affect people's lives. Previous clinical studies on Tong-Xie-Yao-Fang (TXYF) combined with Si-Ni-San (SNS) in the treatment of IBS have been increasing, but there is no systematic evaluation. This study aims to systematically study the effectiveness of TXYF combined with SNS in the treatment of IBS.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 February 2021 and was last updated on 22 February 2021 (registration number INPLASY202120075).

INTRODUCTION

Review question / Objective: **Effectiveness of Tong-Xie-Yao-Fang combined with Si-Ni-San for irritable bowel syndrome.**

Condition being studied: **Irritable bowel syndrome (IBS) has a high morbidity rate worldwide, but there are no effective treatment measures, which seriously affect people's lives. Previous clinical studies on Tong-Xie-Yao-Fang (TXYF) combined with Si-Ni-San (SNS) in the treatment of IBS**

have been increasing, but there is no systematic evaluation. This study aims to systematically study the effectiveness of TXYF combined with SNS in the treatment of IBS.

METHODS

Participant or population: All patients diagnosed with IBS based on specific diagnostic criteria (Rome I criteria, Rome II criteria, Rome III criteria or Rome IV criteria).

Intervention: The treatment of the experimental group is TXYF combined with SNS. The mode of administration is oral, and the dosage form is decoction or granule.

Comparator: The control group was treated with conventional drugs or placebo.

Study designs to be included: All RCTs of TXYF combined with SNS in the treatment of IBS, whether blinded or unblinded.

Eligibility criteria: (1) Non-RCT literature. (2) Animal experiments, case reports and reviews, etc. (3) Repeatedly detected or published literature. (4) Secondary IBS caused by other underlying diseases (5) Unable to obtain complete data or full text literature.

Information sources: The PubMed, EMBASE, Web of Science, the Cochrane Library, China Biomedical Literature (CBM), the Wanfang Chinese digital periodical and conference database, China National Knowledge Infrastructure database (CNKI), and the VIP Chinese Science and Technique Journals Database (VIP) will be searched by us for relevant literature. We will search for data in the above 9 Chinese and English databases, and the search time will from their inception to February, 2021. The key words include "tongxieyaofang", "sinisan", "irritable bowel syndrome", "Irritable Syndrome", "IBS" and "random allocation". We will also search ongoing or unpublished trials from the National Institutes of Health (NIH) clinical registry Clinical Trials, International Clinical Trials Registry Platform (ICTRP) and the Chinese clinical trial registration platform.

Main outcome(s): Total effective rate.

Quality assessment / Risk of bias analysis: The Cochrane collaborative tools will be used to evaluate the quality of the literature.19 The risk assessment of bias includes seven aspects: random sequence generation; hidden grouping; blinding to the research objects and treatment plan implementers; blinding to the outcome measurers; incomplete data; selective reporting of research results; other biases. For each research result, make low-risk, high-risk and unclear judgments on the above 7 items. The quality evaluation is carried out independently and in parallel by two evaluators. In case of inconsistent evaluation results, they must be resolved after discussion.

Strategy of data synthesis: The Review Manager (RevMan) V.5.3 software will be used for statistical analysis. When calculating the effect size, the relative risk (RR) and 95% confidence intervals (CIs) are used for the dichotomous outcomes, and the weighted mean difference (WMD) or standardised mean difference (SMD) will be used for the continuous outcomes.

Subgroup analysis: If there is significant heterogeneity between the research results, we will conduct a subgroup analysis to investigate the differences in age, gender, etc.

Sensitivity analysis: We will also use sensitivity analysis to evaluate the robustness of analysis results.

Country(ies) involved: China.

Keywords: Irritable bowel syndrome, Tong-Xie-Yao-Fang, Si-Ni-San, systematic review, protocol

Contributions of each author:

Author 1 - Jiangwang Jiang - Conceptualization, Software,Writing – original draft, Writing–review & editing.
Email: 1137298371@qq.com

Author 2 - Yun Chen - Formal analysis, Methodology.
Email: 16458551@qq.com
Author 3 - Ziyi Hu - Data curation, Methodology.
Email: huziyi0829@163.com
Author 4 - Huaiyu Li - Data curation, Supervision, Writing – original draft.
Email: 1021504702@qq.com
Author 5 - Jing Ye - Conceptualization, Writing–review & editing.
Email: yejing1016@163.com
Author 6 - Zhiying Yu - Formal analysis, Software.
Email: 1160355864@qq.com
Author 7 - Haiyi Tang - Data curation, Writing–review & editing.
Email: 411070353@qq.com