INPLASY PROTOCOL

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Efficacy and safety of Shouhui Tongbian Capsules in the treatment of constipation : A systematic review and meta-analysis

Guo, X[1]; Li, RR[2]; Huang, NN[3]; Zhang, TY[4]; Li, JC[5]; Gong, LP[6]; Sun, R[7].

Review question / Objective: This study is aimed at systematically evaluating the clinical effect and safety of Shouhui Tongbian Capsules in the treatment of constipation and providing evidence-based references for clinical application.All the studies conducted are RCT studies.

Condition being studied: To obtain comprehensive results, we will search three Chinese electronic databases and three English databases (PubMed, EmBase and the Cochrane Library) . The Chinese databases were the China Network Knowledge Infrastructure (CKNI, https://www.cnki.net/), Wan Fang database (WF, https://www. wanfangdata.com.cn/) and Chinese Scientific Journal Database (http://qikan.cqvip.com/). Two reviewers will search and evaluate the literature separately according to our inclusion and exclusion criteria. NoteExpress (professional software for searching and managing the literature) will be used to identify and remove duplicate or inappropriate studies. Search keywords are as follows: Shouhui Tongbian Capsules, constipation, dyschezia, colonic inertia, chronic constipation, primary constipation, idiopathic constipation, functional constipation, functional defecation disorder, slow transit constipation, irritable bowel syndrome with constipation, constipation of organsecindary constipation, drug constipation, randomized. According to the characteristics of each database, subject words and free words or with the above retrieval words in the full text, theme, topic, keywords, etc.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 October 2022 and was last updated on 19 October 2022 (registration number INPLASY2022100075).

INTRODUCTION

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METHODS

Participant or population: 1310 participants will be included in theanalysis.

Intervention: The intervention measures of the trial group are mainly Shouhui Tongbian Capsules.

Comparator: Western medicine or the basic treatment.

Study designs to be included: RCT.

Eligibility criteria: Diagnostic criteria for constipation (Rome II, Rome III diagnostic efficacy criteria for TCM symptoms,etc.).

Information sources: English databases (PubMed, EmBase and the Cochrane Library) The Chinese databases are the China Network Knowledge Infrastructure (CKNI, https://www.cnki.net/), Wan Fang database (WF, https://www. wanfangdata.com.cn/) and Chinese Scientific Journal Database (http://qikan.cqvip.com/).

Main outcome(s): Total effective rate, clinical symptom Score,gastrointestinal peptide hormone index,safety evaluation.

Quality assessment / Risk of bias analysis: ROB.2.

Strategy of data synthesis: Data analyses will be performed using Review Manager 5.4 and Stata 17.0. Forest plots of outcomes with two or more included studies will be used in meta analysis. Otherwise, the outcomes are systematically assessed. Dichotomous variables are calculated as risk ratio (RR) and standardized mean difference (SMD) with a 95% confidence interval (CI) calculated for continuous outcomes. Heterogeneity in the meta analysis is assessed according to the Cochrane Handbook of Systematic Review of Interventions and tested by Chi-squared and I2 tests. Reasons (sex, age, course and severity of disease, duration, etc.) were analyzed, and a random-effects model was used if there was heterogeneity among the combined analyses (I2 > 40%, P < 0.05). A fixed-effects model is applied if heterogeneity did not exist. To remove the existing heterogeneity, subgroup analysis and sensitivity analysis will be performed on the basis of potential factors. Funnel plots will be used for qualitative analyses of publication bias when there are 10 or more studies included in some meta analyses. Egger test and Bgger test will be used for analysis of publication bias when there are less than 10 studies included in analyses.

Subgroup analysis: The literature will be analyzed by subgroup according to the different dosage and administration time with fixed models are used for analysis.

Sensitivity analysis: Sensitivity analysis will be carried out with the total effective rate, clinical symptom score and serum biochemical indicators as indicators . Single original studies will be removed one by one by removing single studies.

Country(ies) involved: China.

Keywords: Shouhui Tongbian Capsules; Constipation; Meta-analysis.

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