INPLASY PROTOCOL

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None declared.

A Meta-analysis and Experimental Sequential Analysis of Gegen Qinlian Decoction Combined with Conventional Western Medicine in the Treatment of Infective Diarrhea

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Review question / Objective: **In this study, the Meta-analysis and trial sequence analysis were used to evaluate the clinical efficacy and safety of Gegen Qinlian Decoction in combination with conventional western medicine in the treatment of infectious diarrhea in clinical randomized controlled trials. Participants: The subject was definitely diagnosed as infectious diarrhea (age ≥18 years old). Interventions: On the basis of medication in the control group, patients in the treatment group were given symptomatic treatment with compound Gegen Qinlian Decoction. Comparisons: The control group was treated with conventional western medicine. Outcomes: The total clinical efficacy, disappearance time of diarrhea symptoms, disappearance time of abdominal pain symptoms, disappearance time of fever symptoms, interleukin -6 (IL-6) level, tumor necrosis factor-α (TNF-α) level, and adverse reactions were covered, and inclusion in the study must include one of the outcome indicators.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 March 2022 and was last updated on 29 March 2022 (registration number INPLASY202230165).

INTRODUCTION

Review question / Objective: **In this study, the Meta-analysis and trial sequence analysis were used to evaluate the clinical efficacy and safety of Gegen Qinlian Decoction in combination with conventional western medicine in the treatment of infectious diarrhea in clinical randomized controlled trials. Participants: The subject was definitely diagnosed as infectious diarrhea (age ≥18 years old). Interventions: On the basis of medication in the control group, patients in the treatment group were given symptomatic treatment with compound Gegen Qinlian Decoction. Comparisons: The control**

group was treated with conventional western medicine. Outcomes: The total clinical efficacy, disappearance time of diarrhea symptoms, disappearance time of abdominal pain symptoms, disappearance time of fever symptoms, interleukin -6 (IL-6) level, tumor necrosis factor-α (TNF-α) level, and adverse reactions were covered, and inclusion in the study must include one of the outcome indicators.

Condition being studied: We systematically searched seven databases in Chinese and English, including CNKI, WANFANG, VIP, CBM, Embase, PubMed, and Cochrane Library, and searched the clinical randomized controlled trials (RCTs) of Gegen Qinlian Decoction combined with conventional western medicine in the treatment of infectious diarrhea from inception of the database to January 26, 2022. EndNote software was used for literature management. Literature quality was assessed using the Jadad scale and Cochrane risk bias tool; The results of the meta-analysis were combined with effect amount using Review Manager 5.3 software. The stability of Meta-analysis results was analyzed by sensitivity analysis using Stata16.0 software. Clinical efficacy in outcome measures was analyzed sequentially in trials using TSA v0.9 software.

METHODS

Participant or population: In the original study, the subject was definitely diagnosed with infectious diarrhea (age ≥18 years), with no limitation in specific diagnostic criteria, syndrome type, or race, nationality, or gender.

Intervention: On the basis of medication in the control group, patients in the treatment group were given symptomatic treatment with compound Gegen Qinlian Decoction.

Comparator: The control group was treated with conventional western medicine.

Study designs to be included: Clinical randomized controlled trials (RCTs) of Gegen Qinlian decoction combined with conventional Western medicine methods for the treatment of Infective Diarrhea published in domestic and foreign journals.

Eligibility criteria: None.

Information sources: China journal full-text database (CNKI), WANFANG data knowledge service platform (Wang Fang), VIP Chinese science and technology journal full-text database (VIP), China biomedi.

Main outcome(s): The total clinical efficacy, disappearance time of diarrhea symptoms, disappearance time of abdominal pain symptoms, disappearance time of fever symptoms, interleukin -6 (IL-6) level, tumor necrosis factor-α (TNF-α) level, and adverse reactions were covered, and inclusion in the study must include one of the outcome indicators.

Quality assessment / Risk of bias analysis: The Cochrane Collaboration's risk assessment tool for bias and the Jadad scale were used for quality evaluation of included studies.

Strategy of data synthesis: (1) heterogeneity test and Meta-analysis: RevMan 5.3 software was used for heterogeneity test and Meta-analysis data processing. i can be used to determine the magnitude of heterogeneity, when $p > 0.1$, $i < 50\%$, indicating that there was no heterogeneity between studies, and the fixed-effect model was selected for meta-analysis; When $P < 0.1$, and $I \geq 50\%$, the heterogeneity between studies existed. The random effect model was selected for Meta-analysis, and the source of heterogeneity adopted subgroup analysis or descriptive analysis. Relative risk (RR) and 95% confidence interval (95%CI) were used for effect amount combination of the two categorical variables, and weighted mean difference (WMD) and 95% CI (95%CI) were used for effect amount combination of the continuity variables. (2) Sensitivity analysis: The original studies were excluded one by one and the remaining studies were combined with effect amount using Stata 16 software. The

stability of the results of the meta-analysis was evaluated by comparing the combined results of the old and the new effects. (3) Risk assessment of bias: For outcome indicators that included ≥10 items in the study, the inverted funnel plot in RevMan 5.3 software was used to assess the potential publication bias. (4) trial sequential analysis: The TSA v0.9 software developed by Copenhagen trial unit (CTU) was used for trial sequential analysis to determine the impact of random errors on the results of the Meta-analysis, and to reduce the occurrence of "Class I errors" in the Meta-analysis, thereby improving the credibility of the study.

Subgroup analysis: According to the disappearance time of abdominal pain symptoms, the heterogeneity test showed that there was moderate heterogeneity between the groups, so it was divided into two subgroups for analysis according to the course of medication.

Sensitivity analysis: These sources of heterogeneity were related to the period of the disease between studies, the dosage of Zhigancao decoction, and the number of samples in the experiment.

Country(ies) involved: China.

Keywords: Gegen Qinlian Decoction; Infectious diarrhea; Meta Analysis; Test sequential analysis.

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