

INPLASY PROTOCOL

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Corresponding author:
Yongheng He

320034@hnucm.edu.cn

Author Affiliation:
Hunan Academy of traditional Chinese Medicine Affiliated Hospital.

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Conflicts of interest:
None declared.

Tianshu (ST25) for functional gastrointestinal disorders: a protocol for systematic review and meta-analysis

Wang, H¹; Ding, N²; Tang, Y³; He, Y⁴.

Review question / Objective: The purpose of this study is to assess the efficacy of Tianshu (ST25) in the treatment of functional gastrointestinal disorders (FGIDs) such as irritable bowel syndrome (IBS), functional dyspepsia (FD), and functional constipation (FC).

Condition being studied: Randomized controlled trials (RCTs) will be considered if they enrolled patients with FGIDs in order to evaluate the effect of Tianshu (ST25).

Eligibility criteria: (1) RCTs with any length of follow-up and sample size; (2) individuals (18-75 years old) with FD, IBS, or FC; diagnostic criteria included but not limited to the Rome criteria; (3) The intervention group will include all types of traditional Chinese medicine external treatment methods of Tianshu (ST25), such as acupuncture, warm acupuncture, moxibustion, electro-acupuncture, massage, cupping, and clinical trials combined with other therapies; the control group will include those who received sham acupuncture, medication treatment, no (specific) treatment, or Tianshu (ST25) as a combination therapy to another treatment; (4) reported quantitative outcomes.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 April 2022 and was last updated on 24 April 2022 (registration number INPLASY202240145).

INTRODUCTION

Review question / Objective: The purpose of this study is to assess the efficacy of Tianshu (ST25) in the treatment of functional gastrointestinal disorders (FGIDs) such as irritable bowel syndrome

(IBS), functional dyspepsia (FD), and functional constipation (FC).

Condition being studied: Randomized controlled trials (RCTs) will be considered if they enrolled patients with FGIDs in order to evaluate the effect of Tianshu (ST25).

METHODS

Participant or population: Patients with functional gastrointestinal disorders (FGIDs) such as irritable bowel syndrome (IBS), functional dyspepsia (FD), and functional constipation (FC).

Intervention: Tianshu (ST25).

Comparator: The control group.

Study designs to be included: RCTs.

Eligibility criteria: (1) RCTs with any length of follow-up and sample size; (2) individuals (18-75 years old) with FD, IBS, or FC; diagnostic criteria included but not limited to the Rome criteria; (3) The intervention group will include all types of traditional Chinese medicine external treatment methods of Tianshu (ST25), such as acupuncture, warm acupuncture, moxibustion, electro-acupuncture, massage, cupping, and clinical trials combined with other therapies; the control group will include those who received sham acupuncture, medication treatment, no (specific) treatment, or Tianshu (ST25) as a combination therapy to another treatment; (4) reported quantitative outcomes.

Information sources: The following databases will be searched: Medline, the Cochrane Library, EMBASE, Web of Science, and the CENTRAL, CBM, CNKI, VIP, and Wanfang databases.

Main outcome(s): The total effective rate.

Quality assessment / Risk of bias analysis: Using the Cochrane Collaboration risk of bias tool, two researchers independently assessed the methodological quality of all included trials using seven factors, and the RCTs were categorized as “high risk”, “low risk”, or “uncertain”. If required, we will attempt to contact the authors through e-mail for more details.

Strategy of data synthesis: The Stata 14.0 software package will be utilized. Continuous data will be given as the

standardized mean difference (SMD) with a 95 percent confidence interval (CI), whereas dichotomous data will be displayed as the odds ratio (OR) with a 95 percent CI.

Subgroup analysis: The treatments, sample size, and duration will be used to establish subgroups.

Sensitivity analysis: The reliability and stability of the pooled results will be evaluated using sensitivity analysis.

Country(ies) involved: China.

Keywords: Tianshu (ST25), functional gastrointestinal disorders, irritable bowel syndrome, functional dyspepsia, functional constipation, meta-analysis.

Contributions of each author:

Author 1 - Huashuai Wang.
Email: 20192035@stu.hnucm.edu.cn
Author 2 - Ning Ding.
Email: 2974424630@qq.com
Author 3 - Yanbo Tang.
Email: 374437987@qq.com.
Author 4 - Yongheng He.
Email: 320034@hnucm.edu.cn