# INPLASY PROTOCOL

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**The authors have no conflicts of interest to disclose.**

# Acupuncture for opioid-induced constipation: Protocol for a systematic review and meta-analysis

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**Review question / Objective:** **This study will present an assessment of the efficacy and safety of acupuncture treatment for OIC patients through summarize high-quality clinical evidence.**
**Condition being studied:** **OIC is the most common and bothersome problem for patients with chronic taking opioids therapy, it affects 60%-90% of cancer patients with opioids. It has been reported that about 215 million prescriptions for opioids in the United States in 2019. OIC occurs primarily related to u-opioid receptor activation in the gut that reduces rectal sensation, decreases peristalsis and increases colonic fluid absorption. This results in harder stools. The National Comprehensive Cancer Network (NCCN) guidelines referred that the prevention and treatment of adverse reactions are an important part of the analgesic therapy plan. Once opioids are used, the prescription laxatives should be implemented to treatment OIC. However, laxatives do not target the underlying cause of opioid binding to the u-receptors in the enteric system and as such are not very effective at managing OIC. Accordingly, it is essential to find an alternative treatment.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 October 2020 and was last updated on 09 October 2020 (registration number INPLASY2020100026).

## INTRODUCTION

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occurs primarily related to u-opioid receptor activation in the gut that reduces rectal sensation, decreases peristalsis and increases colonic fluid absorption. This results in harder stools. The National Comprehensive Cancer Network (NCCN) guidelines referred that the prevention and treatment of adverse reactions are an important part of the analgesic therapy plan. Once opioids are used, the prescription laxatives should be implemented to treatment OIC. However, laxatives do not target the underlying cause of opioid binding to the u-receptors in the enteric system and as such are not very effective at managing OIC. Accordingly, it is essential to find an alternative treatment.

## METHODS

**Participant or population:** The study will include patients who were clinically diagnosed with OIC. There is no restriction on age, gender, or nationality. Besides, the diagnostic criteria are based on the Rome III criteria.

**Intervention:** Acupuncture and related treatments, regardless of needle material, acupoint selection, duration of treatment, acupuncture manipulation.

**Comparator:** The control group are treated with drugs, placebo, sham acupuncture, or other conventional therapy, either.

**Study designs to be included:** All randomized controlled trials (RCTs) of acupuncture therapy for OIC will be included in the study, while animal experiments, cluster RCTs, reviews, and case reports will be excluded.

**Eligibility criteria:** Type of studies. All randomized controlled trials (RCTs) of acupuncture therapy for OIC will be included in the study, while animal experiments, cluster RCTs, reviews, and case reports will be excluded. Types of participants. The study will include patients who were clinically diagnosed with OIC. There is no restriction on age, gender, or nationality. 2.2.3. Types of intervention. The patients in the intervention group adopt acupuncture and related treatments, regardless of needle material, acupoint selection, duration of treatment, acupuncture manipulation, while the patients in the control group are treated with drugs, placebo, sham acupuncture, or other conventional therapy, either. 2.3. Types of outcome measures 2.3.1. Primary outcomes. The primary efficacy outcomes measure will be as follows: changes in the Bowel Function Index (BFI) score or Cleveland Constipation Score (CCS). 2.3.2. Secondary outcomes. The secondary outcome measures will include the Patient Assessment of Constipation Quality of Life.

**Information sources:** We will search for PubMed, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI), Wan-Fang Data (WF), Chinese Scientific Journal Database (VIP), Chinese Biological and Medical Database (CBM) literature databases from its inception to September 2020 with a language restriction on Chinese or English.

**Main outcome(s):** Bowel Function Index (BFI) score or Cleveland Constipation Score (CCS).

**Additional outcome(s):** Constipation Quality of Life (PAC-QOL) questionnaire and adverse effects linked to interventions.

**Quality assessment / Risk of bias analysis:** The risk of bias assessment of the included RCTs will be evaluated by using the risk of bias assessment tool of the Cochrane Handbook, version 5.1.0, which includes 7 items as following: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, other bias. This evaluation will be conducted by two independent reviewers according to a judgment for literature that will be categorized as low bias, unclear bias, or high bias.

**Strategy of data synthesis:** RevMan 5.3 software will be used for data synthesis and analysis. When the outcome data is a

**binary variable, select the relative risk (RR) as the effect scale; when the outcome data is a continuous variable, use the mean difference (MD) and standardized mean difference (SMD) as an effect scale, both calculated by 95% confidence interval (CI).**

**Subgroup analysis: If significant heterogeneity is detected between a group of studies, subgroup analysis will be performed based on acupuncture types, countries, treatment courses, the control group intervention measures.**

**Sensibility analysis: If the heterogeneity is significant, we will conduct a sensitivity analysis according to eliminating each of the included studies one by one, and changing the effect scale of studies to evaluate the robustness and quality of the conclusion in the studies.**

**Language: Chinese and English.**

**Country(ies) involved: China.**

**Keywords: acupuncture, opioid-induced constipation, meta-analysis, systematic review, protocol.**

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