

# INPLASY PROTOCOL

To cite: Sun et al. Acupoint Application Therapy for Rotavirus Diarrhea in Infants and Children: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Inplasy protocol 202070123. doi: 10.37766/inplasy2020.7.0123

Received: 28 July 2020

Published: 28 July 2020

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**Support:** Natural science foundation.

**Review Stage at time of this submission:** Preliminary searches.

**Conflicts of interest:**  
All authors declare that they have no conflict of Interest.

## Acupoint Application Therapy for Rotavirus Diarrhea in Infants and Children: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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**Review question / Objective:** Rotavirus is responsible for more than one-third of diarrhea-associated deaths in children under 5 years of age even though the vaccination. Key treatment concepts including fluid and electrolyte management, dietary management. Acupoint Application, as one of the traditional Chinese medicine (TCM) therapies, consist of a system of noninvasive therapeutic procedures of applying processed Chinese herbal medicine formulations to acupoints. Acupoint Application has been used for a long time in infants and children in China. Acupoint application is simple and safe, so it is worth popularizing in the treatment of pediatric diseases because it is easy to be accepted by children. However, studies about therapeutic effect of acupoint application have not reached consistent conclusions. As studies about acupoint application treating rotavirus diarrhea accumulated, we want to explore the effect of acupoint application on rotavirus diarrhea, and we perform a systematic review and meta-analysis to provide an evidence to clinic doctor.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 July 2020 and was last updated on 28 July 2020 (registration number INPLASY202070123).

### INTRODUCTION

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**Condition being studied:** Diarrheal disease currently claims the lives of approximately 500,000 children each year. Rotavirus is mainly responsible for more severe cases and more than one-third of diarrhea-associated deaths in children under 5 years old globally. Rotavirus vaccine rollout has decreased the global proportion of hospitalized diarrhea cases attributed to rotavirus among children younger than 5 years from 38.0% to 23.0%. However, present rotavirus vaccines have many weaknesses—they are highly effective in preventing severe rotavirus disease in developed countries; however, preliminary efficacy studies in Africa and Asia have found that rotavirus vaccines are less effective in preventing severe rotavirus diseases than in developed countries, with wide differences by region. We therefore performed a meta-analysis of currently available randomized controlled studies to evaluate the effectiveness of acupoint application therapy for rotavirus diarrhea treatment.

## METHODS

**Search strategy:** We searched the relevant medical literature using PubMed, Embase, Web of Science, Cochrane Central, and China National Knowledge Infrastructure

(CNKI), VIP, WANGFANG from inception to July 2020. Both MeSH and free text terms were utilized to obtain maximum numbers of papers. There will be no language or district restrictions.

**Participant or population:** Inclusion criteria: 1. The search for studies are limited to RCTs. 2. Infants and children younger than 14 year. 3. The diarrhea is caused by rotavirus, and rotavirus diarrhea was diagnosed based on symptoms and stool examinations. 4. with a duration of less than 3 days. 5. Diarrhea is usually defined as three or more loose stools in a 24-h period. Exclusion criteria: 1. Patients with infectious diarrhea other than rotaviral diarrhea. 2. patients with other systemic diseases. 3. Those with history of malabsorption syndromes.

**Intervention:** Acupoint application.

**Comparator:** Placebo or any other compared standard drugs or clinical intervention.

**Study designs to be included:** Meta-analysis, Systematic reviews.

**Eligibility criteria:** (1) RCTs; (2) infants and children  $\leq 6$  years; (3) patients from developing countries; (4) diarrhea was caused by rotavirus, and rotavirus diarrhea was diagnosed based on symptoms and stool tests; (5) duration of diarrhea  $\leq 3$  days; and (6) diarrhea was defined as three or more loose stools in a 24 h period.

**Information sources:** We search the relevant medical literature using PubMed, Embase, Web of Science, Cochrane Central, and China National Knowledge Infrastructure (CNKI), VIP, WANGFANG electronic database.

**Main outcome(s):** 1. duration of diarrhea. 2. Clinical cure rate or Frequency of diarrhea.

**Additional outcome(s):** (1) duration of fever, (2) duration of vomiting, (3) duration of hospitalization, (4) ORS intake, and (5) adverse events.

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**Data management:** All acupoint application therapy for treatment of rotavirus diarrhea in infants and children were included in this review, and we only choose Randomized controlled trials (RCTs). The data includes: author, year of publication, study design, age of patients, type of intervention, control group, diarrhea duration and the outcomes.

**Quality assessment / Risk of bias analysis:** Three independent authors assessed the risk of bias of included studies using a modification of the Cochrane Handbook for Systematic Reviews of Interventions, according to the following details: 1. selection bias: random sequence generation and allocation concealment; 2. performance bias and detection bias: blinding; 3. attrition bias: incomplete outcome data; 4. reporting bias: selective reporting; and 5. other bias: premature completion. Each item was assessed as “low risk”, “unclear risk” or “high risk”. Three authors discussed and solved the possible disagreements.

**Strategy of data synthesis:** Data will be analyzed by using the Cochrane Collaboration Review Manager Version 5. The mean and Standard deviation will be calculated to represent the outcomes with the corresponding 95% confidence intervals (95% CI). Statistical heterogeneity was assessed by  $I^2$  statistics. According to the heterogeneity between included studies, fixed effect model or random effects model will be chosen. We will consider the heterogeneity as significant if p-value 0.05 or  $I^2$  value 50%. When heterogeneity exists, sensitivity analyses will be used to explore heterogeneity sources.

**Subgroup analysis:** Subgroups analysis will be used to explain heterogeneity, if we have an enough studies. We hypothesized that difference in etiology, area, age and breast milk or baby formula may act as effect modifiers.

**Sensibility analysis:** Sensibility analysis will be calculated and assessed with Stata

software (version 14.0, StataCorp, College Station, TX).

**Language:** There is no language restrictions.

**Country(ies) involved:** There is no countries restrictions.

**Keywords:** Acupoint Application Therapy, Rotavirus diarrhea, Meta-ananlysis, infants and children, randomized controlled trials.

**Contributions of each author:**

Author 1 - Shaodan Sun - Shaodan Sun will perform the data analyses and write the manuscript.

Author 2 - Xiaojie Lin - data analysis and manuscript preparation.

Author 3 - Yang Yang - data analysis and manuscript preparation.

Author 4 - Jingtuo Ceng - Jingtuo ceng will help perform the analysis with constructive discussions.

Author 5 - Fei Luo - Fei Luo will help perform the analysis with constructive discussions.

Author 6 - Xiaogang Chen - Xiaogang Chen conceived and designed the study.