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Fire dragon cupping for pediatric vomiting

Submission date 28/01/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 09/02/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 05/02/2026	**Condition category** Signs and Symptoms	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
Fire dragon cupping combined with acupoint application for treating vomiting in children with spleen-stomach deficiency cold pattern: a randomised controlled trial

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/01/2025, Rugao Traditional Chinese Medicine Hospital (No. 269, Dasi Road, Rucheng Street, Rugao City, Nantong, 226500, China; +86 (0)513 87512380; rgszyyyb@163.com), ref: RGSZYYLL25019

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Pediatric vomiting

Interventions
Participants were randomized 1:1 via computer-generated sequences, allocation concealed in sequentially numbered, opaque, sealed envelopes.

Control Group:
Children received dietary management (short-term fasting if needed, followed by a warm, bland, easily digestible diet with frequent small meals) and abdominal warmth, alongside TCM acupoint application. A medicinal paste was made from powdered Evodia rutaecarpa (5 g), monkshood (5 g), dried ginger (5 g), cassia twig (5 g), and asarum (3 g) mixed with honey, formed into a cake (2 cm diameter, ~0.2 cm thick), and placed on a 6 × 6 cm breathable patch (Cofoe). The patch was applied to cleansed skin at Shenque, Zhongwan, Neiguan, and Zusanli acupoints for 4–6 hours daily for 3 days. Any discomfort, itching, redness, or swelling was to be reported immediately.

Observation Group:
This group received the control group treatment plus comprehensive moxibustion using a fire dragon jar. Treatment emphasized the Ren meridian, with additional focus on the Du and Stomach meridians and Back-Shu points. Using a small bell-shaped jar containing a burning moxa cone, techniques included rotating, opening/closing the jar, acupressure, vibration, pushing, kneading, and hot compress. Children were positioned comfortably with skin lightly lubricated. In the supine position, the abdomen was treated (outside to inside) with emphasis on Zhongwan, Shenque, Guanyuan, Tianshu, and Daheng acupoints for 10–15 minutes. In the prone position, the back was treated along the Du meridian (Zhiyang to Dazhui) and the Bladder meridian (Fengmen to Weishu), focusing on Zhiyang, Dazhui, Pishu, and Weishu for 5–10 minutes.

Treatment was given once daily for 3 days. Manipulation was gentle, stopping at slight skin redness and sweating to prevent burns. Post-treatment, children drank warm water, avoided wind/cold, and refrained from bathing on the day of treatment.

Intervention Type
Other

Primary outcome(s)
1. Primary symptoms (vomiting, loss of appetite) and secondary symptoms (nausea, abdominal pain, loose stools, fatigue, pallor, etc) measured using TCM Syndrome Rating Scale for Infantile Vomiting with Syndrome of Deficient Cold of Spleen and Stomach at before and after treatment

2. Clinical symptom disappearance time (vomiting, nausea, abdominal pain, poor appetite, loose stools) measured using family inquiry and physical examination at fixed daily intervals throughout the trial

3. Clinical efficacy measured using the Guiding Principles for Clinical Research of New Chinese Medicine at post-treatment

4. Adverse events (AEs) and serious AEs (SAEs) measured using monitoring and recording at throughout the trial

5. Family satisfaction measured using a self-designed 4-point Likert scale survey at post-treatment

Key secondary outcome(s)

Completion date
21/10/2025

Eligibility

Key inclusion criteria
Children were included if they:
1. Met the diagnostic criteria for infantile vomiting (spleenstomach deficiencycold pattern) according to both Western medicine (Zhu Futang Practice of Pediatrics, 9th Edition) and TCM (Diagnostic and Therapeutic Efficacy Standards for Traditional Chinese Medicine Diseases and Syndromes)
2. Were aged 1–6 years
3. Presented with acute illness (≤48 hours) and mildtomoderate vomiting severity (1–9 episodes /day) on the Nausea and Vomiting Gastric Dynamics Scale (NVG)
4. Had not used antiemetic/prokinetic drugs within 24 hours before enrollment
5. Had not participated in other clinical trials within the past 3 months
6. Had legal guardians who provided written informed consent

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 Years

Upper age limit
6 Years

Sex
All

Total final enrolment
114

Key exclusion criteria
1. Vomiting due to other defined causes (e.g., intracranial hypertension, acute abdomen, intestinal obstruction, metabolic disorders)
2. Severe primary disease or mental disorder affecting cooperation
3. Known allergy to any drug or material used in the study (e.g., monkshood, asarum, ginger, moxa ash)
4. Skin lesions, eczema, dermatitis, ulcers, or scars at treatment sites
5. Severe NVG grading (projectile vomiting ≥10 times/day, or complications such as dehydration /electrolyte imbalance)

Date of first enrolment
09/01/2025

Date of final enrolment
06/08/2025

Locations

Countries of recruitment
China

Sponsor information

Organisation
Rugao Traditional Chinese Medicine Hospital

Funder(s)

Funder type

Funder Name
Nantong Municipal Health Commission Research Project

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available