Acupuncture for children with functional constipation: a pilot study

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To evaluate the feasibility, safety and potential efficacy of acupuncture in children with FC. The results of this study will be used to design a future randomized controlled trial (RCT).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational invasive

Summary

ID

NL-OMON57236

Source
ToetsingOnline

Brief title
ACU-PILOT

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
constipation, functional constipation

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Stichting Emma Kinderziekenhuis

Intervention

Keyword: acupuncture, children, constipation

Outcome measures

Primary outcome

The primary endpoint is feasibility: a future RCT using this same intervention protocol will be deemed feasible if the pilot study renders an attrition rate >=70% (i.e. >=70% of patients completing the pilot study while attending >=75% of scheduled acupuncture sessions).

Secondary outcome

Other feasibility endpoints include: consent rate, patient and parent satisfaction and required personnel capacity. Safety endpoints: adverse events and serious adverse events will be evaluated. Treatment success is the main efficacy endpoint, this definition is based on the Rome IV criteria; a child who no longer fulfills the Rome IV criteria at the end of the intervention period is considered successfully treated. Other efficacy endpoints are based on a previously published core outcome set and include: defecation frequency, stool consistency, painful defecation, fecal incontinence frequency, abdominal pain, use of (escape) medication and quality of life.

Study description

Background summary

Functional constipation (FC) is common in children and poses a significant burden to patients, their families and the healthcare system. Pharmacological treatment mainly consists of oral osmotic laxatives. However, poor adherence to oral laxatives is known to be a common problem and patients often remain symptomatic despite pharmacological treatment. Many parents seek help in the form of complementary and integrative medicine. Acupuncture has been shown to relieve symptoms in adults with FC. However, published studies in children with

FC are scarce and have important limitations.

Study objective

To evaluate the feasibility, safety and potential efficacy of acupuncture in children with FC. The results of this study will be used to design a future randomized controlled trial (RCT).

Study design

A prospective, non-randomized, multicenter, open-label pilot study.

Intervention: Children will receive 8 acupuncture sessions during 10 weeks (1 session per week during 6 weeks, followed by 1 session every other week during 4 weeks). Concurrent pharmacological treatment with polyethylene glycol >= 0.2 g/kg/day will be maintained as initiated prior to participation in the study.

Study burden and risks

During this study, patients will visit the hospital or acupuncture facility in Amsterdam 10 times in 14 weeks. They will receive 8 acupuncture treatments. Patients/parents are asked to fill out several questionnaires throughout the study, including questions about defecation frequency, adverse events, quality of life, school absenteeism and treatment satisfaction. Outcomes of systematic reviews on the efficacy and safety of acupuncture in pediatric practice conclude that acupuncture treatment is well-tolerated and the majority of reported adverse events associated with pediatric needle acupuncture are infrequent and mild. Randomized sham-controlled studies in adults with FC report low adverse event rates in both sham and acupunctures groups, all reported adverse events were mild and transient. In a recent meta-analysis evaluating the safety of acupuncture in adults with FC, no significant difference with regard to safety was found between acupuncture and treatment with polyethylene glycol, and acupuncture was considered safer than lactulose and mosapride.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- 6-18 years of age
- meet the modified Rome IV criteria for FC (defined as meeting at least two of the following criteria during the 2-week run-in period despite receiving treatment with PEG with a minimum dose of 0.2 g/kg/day):
1. Two or fewer spontaneous bowel movements (SBMs) per week (an SBM is defined as a bowel movement that occurs in the absence of laxative, enema, or suppository use in the preceding 24 hours)
2. History of excessive stool retention
3. History of painful or hard bowel movements
4. History of large-diameter stools
5. Presence of a large fecal mass in the rectum
6. At least 1 episode/week of incontinence after the acquisition of toileting skills
7. History of large-diameter stools that may obstruct the toilet in toilet-trained children
- Insufficient symptom management despite at least three months of medical management (including education, non-pharmacological advice and laxatives) by a physician. Insufficient symptom management is defined as the presence of at

least one of the Rome IV criteria for FC despite medical management by a physician.
- are treated with PEG with a minimum dose of 0.2 g/kg/day for a minimum of 1 month prior to inclusion in the study
- Written informed consent obtained from parents or guardians and all children >=12 years.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- children with FC not treated with PEG with a minimum dose of 0.2g/kg/day during at least one month at the time of potential inclusion.
- Irritable bowel syndrome.
- Organic causes of constipation; e.g. celiac disease, pediatric intestinal pseudo-obstruction, hypothyroidism, spina bifida, anorectal malformations, or Hirschsprung disease.
- Significant chronic health conditions requiring specialty care (e.g. cardiac, pulmonary, hepatic, hematopoietic, renal, endocrine, or metabolic diseases, sickle cell disease, cerebral palsy) that could potentially impact the child*s ability to participate or confound the results of the study.
- Unintentional weight loss greater than or equal to 5% of their body weight within the last 3 months.
- Gastrointestinal blood loss.
- Recurrent or unexplained fevers.
- Pregnancy.
- Smoking.
- History of abdominal surgery involving the luminal gastrointestinal tract, except appendectomy or hernia repairs.
- Concomitant use of drugs that are known to affect gastrointestinal motility.
- Established diagnoses of autism spectrum disorders.
- Major psychiatric disorders (bipolar disorder, schizophrenia, major depression) or a history of abuse.
- Severe needle-related anxiety.
- Rash or active local infection over an acupuncture point.
- Immunocompromised children (specifically inadequately regulated diabetes mellitus, active staphylococcal-related skin conditions)
- Clotting disorders or a recent history of thrombocytopenia.
- Children who previously received acupuncture for constipation.
- Children who currently participate in another clinical trial.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-02-2025
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	17-01-2025
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL87083.018.24