# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Effect of visceral manipulation on children with chronic functional constipation

## Protocol summary

**Study aim**
Effect of visceral manipulation on children with chronic functional constipation

**Design**
Clinical trial with control group, with parallel groups, one blind, randomized

**Settings and conduct**
This study is a clinical trial conducted in physiotherapy clinics of the Jundishapur University of Medical Sciences in Ahvaz on children with functional constipation. Children aged 5 to 18, who according to the gastroenterologist, have chronic functional constipation, are assessed in terms of inclusion and exclusion criteria, which, if they are eligible, are included in the study, then the subjects were randomly assigned to control and intervention groups then the evaluator who is not aware of the type of patient group will measure the variables specified. In both control and intervention groups, standard medical treatments are given, but only in the intervention group patients are given 2 times per week for 4 weeks of treatment with visceral manipulation techniques. At the end of the week, the variables in the two groups are reassessed by the evaluator.

**Participants/Inclusion and exclusion criteria**
The conditions of entry include functional constipation, age 5-18 and duration of affection at least 3 months, and non-entry conditions including metabolic and endocrine disorders, Hirschsprung's disease, Down syndrome, neurological and neurological disorders, and congenital anorectal malformations.

**Intervention groups**
The groups included control and intervention groups. In both groups, standard medical treatments, including medication, nutritional and behavioral counseling are applied, but in the intervention group, the visceral manipulation techniques is also used.

**Main outcome variables**
Abdominal Pain; Defecation Pain; Fecal Consistency; Stool Frequency; Dose of Laxative

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190614043891N1**
Registration date: **2019-12-04, 1398/09/13**
Registration timing: **prospective**

Last update: **2019-12-04, 1398/09/13**
Update count: **0**

**Registration date**
2019-12-04, 1398/09/13

**Registrant information**

**Name**
Syed Arman Zkaryaei

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 61 3743 1013

**Email address**
armanzakaryaei22@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-12-22, 1398/10/01

**Expected recruitment end date**
2020-03-18, 1398/12/28

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

Effect of visceral manipulation on children with chronic functional constipation

**Public title**
Effect of viseral manipulation in constipation
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
All children with Functional constipation aged 5 to 18 years At least 3 months have passed since they occurred
**Exclusion criteria:**
Endocrine and Metabolic disorders (eg, Hypothyroidism, Hypercalcemia, Diabetes mellitus) Neurologic and Psychiatric disorders(Spina bifida, Cerebral palsy, Autism) Hirschsprung'sdisease and Down's syndrome Congenital anorectal malformation
**Age**
From **5 years** old to **18 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **20**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study, block randomization will be used to assimilate the number of samples in control and treatment groups. This randomization is performed among patients with functional constipation referred to Abu Dhar Hospital. The blocks consist of 6 blocks of 4 that 5 blocks will select between the 6 possible modes of the blocks . In these blocks, the letter A is assigned to the control group and the letter B to the treatment group.Depending on the order of the letters A and B at the time of referral, the patient falls into the control or treatment group.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
In this study, the person evaluating outcomes is unaware of the type of grouping and treatments applied to each group. Also, the data analyzer is not aware of the relationship between the data and the type of group and merely compiles statistical analyzes on data collection.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
**Street address**
Ahvaz Jundishapur University of Medical Sciences, Faculty of Rehabilitation Sciences
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
1579461357
**Approval date**
2019-07-15, 1398/04/24
**Ethics committee reference number**
IR.AJUMS.REC.1398.293

## Health conditions studied

### 1

**Description of health condition studied**
Constipation
**ICD-10 code**
K59.9
**ICD-10 code description**
Functional intestinal disorder, unspecified

## Primary outcomes

### 1

**Description**
Bristol scale score that measure the consistency and shape of the stool
**Timepoint**
At the beginning of the study (before the intervention) and 28 days after the intervention
**Method of measurement**
Bristol Stool Form Scale

### 2

**Description**
Score of defecation pain
**Timepoint**
At the beginning of the study (before the intervention) and 28 days after the intervention
**Method of measurement**
Wong-Baker Faces Pain Rating Scale

### 3

**Description**
Score of abdominal pain
**Timepoint**
At the beginning of the study (before the intervention)

and 28 days after the intervention

**Method of measurement**

Wong-Baker Faces Pain Rating Scale

**4**

**Description**

Number of defecation per week

**Timepoint**

At the beginning of the study (before the intervention) and 28 days after the intervention

**Method of measurement**

Patient report

## Secondary outcomes

**1**

**Description**

Dosage of laxative drug

**Timepoint**

At the beginning of the study (before the intervention) and 28 days after the intervention

**Method of measurement**

Patient report

## Intervention groups

**1**

**Description**

Intervention group: In the intervention group, in addition to the standard medical treatments that are given in both groups, visceral manipulation techniques are applied for four weeks and two weeks each week for these patients.

**Category**

Rehabilitation

**2**

**Description**

Control group: Interventions in this group are standard medical treatments. These treatments include the use of medicines prescribed by the pediatric gastroenterologist, parents and children's education about the symptoms of the disease, nutritional counseling (the effect of fluid and fiber intake), and behavioral training.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Majid Ravanbakhsh

**Street address**

Ahvaz Jundishapur University of Medical Sciences, Faculty of Rehabilitation Sciences

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

61357-15794

**Phone**

+98 61 3743 1013

**Fax**

+98 61 3374 3506

**Email**

Ahvaz-rehab@ajums.ac.ir

**Web page address**

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Badavi

**Street address**

Golestan

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

61357-15794

**Phone**

+98 61 3336 2414

**Fax**

+98 61 3336 1544

**Email**

itc@ajums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**
Majid Ravanbakhsh
**Position**
Associate professo
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Physiotherapy
**Street address**
Golestan
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
33133 -61357
**Phone**
+98 61 3743 1013
**Fax**
+98 61 3374 3506
**Email**
majidravanbakhsh@yahoo.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Majid Ravanbakhsh
**Position**
Assistant professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Physiotherapy
**Street address**
Golestan
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
33133 -61357
**Phone**
+98 61 3743 1013
**Fax**
+98 61 3374 3506
**Email**
majidravanbakhsh@yahoo.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Syed Arman Zkaryaei
**Position**
Masters student
**Latest degree**
Bachelor
**Other areas of specialty/work**
Physiotherapy
**Street address**
Golestan
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
15794 -61357
**Phone**
+98 61 3743 1013
**Fax**
+98 61 3374 3506
**Email**
armanzakaryaei22@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Not applicable
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available
**Title and more details about the data/document**
The whole potential data is published after being unidentifiable
**When the data will become available and for how long**
6 months after printing the results
**To whom data/document is available**
Data will be available only to researchers working in academic and scientific institutions
**Under which criteria data/document could be used**
If someone wants to do the same research project
**From where data/document is obtainable**
Executor of plan: Dr.Majid ravanbakhsh E-mail: majidravanbakhsh@yahoo.com
**What processes are involved for a request to access data/document**
By sending an E-mail with a full explanation of the reason for requesting the documentation and the purpose of having it
**Comments**