# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Evaluation of the anti-constipation effects of abdominal application of olive oil ointment in children 1-4 years old: A double-blind, randomized clinical trial

## Protocol summary

**Summary**

Constipation is the most prevalence gastrointestinal disease in children with prevalence of 0.8-25%. In Traditional Persian Medicine, medicinal plants play an important role in the treatment of constipation. Among them, oral use and topical application of olive oil has been widely recommended. In the present study, children 1-4 years of age which have been diagnosed with functional constipation according NASPGHAN, Rome III criteria were included for two weeks. The patients were randomly divided into two groups. The intervention group received an ointment containing 85% olive oil two times daily. The placebo group received an ointment containing 85% of liquid paraffin whose color and smell were adjusted to be similar to that of intervention ointment. Both ointments were applied on abdominal area with circular massage for 5 minutes. The application method was taught to children's caregivers. Patients are being visited by Pediatric specialist every three days.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017072535304N1**
Registration date: **2017-09-11, 1396/06/20**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2017-09-11, 1396/06/20

**Registrant information**

**Name**

Hossein Arman asl

**Name of organization / entity**

Mashhad University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 51331801

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**Recruitment status**

**Recruitment complete**

**Funding source**

Research council, Mashhad University of Medical Sciences

**Expected recruitment start date**

2017-09-23, 1396/07/01

**Expected recruitment end date**

2018-06-22, 1397/04/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the anti-constipation effects of abdominal application of olive oil ointment in children 1-4 years old: A double-blind, randomized clinical trial

**Public title**

Evaluation of the anti-constipation effects of abdominal application of olive oil ointment in children 1-4 years old: A double-blind, randomized clinical trial

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: The presence of two or more of the NASPGHAN, Rome III criteria for at least one month: Two or fewer defecations in the toilet per week At least one

episode of faecal incontinence per week History of retentive posturing or excessive volitional stool retention History of painful or hard bowel movements Presence of a large faecal mass in the rectum History of large diameter stools which may obstruct the toilet. Exclusion criteria:Organic constipation, Hypothyroidism, intestinal pseudo-obstruction, cystic fibrosis, neural anomalies, intestinal obstruction, constipation-inducing medications such as calcium and iron containing supplements, anti-histamines, tricyclic antidepressants, antacids, etc.

**Age**
From **1 year** old to **4 years** old

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **50**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Regional Committee for Research Ethics, Mashhad University of Medical Sciences

**Street address**
Ghoreishi building, Daneshgah Street

**City**
Mashhad

**Postal code**
91775-1365

**Approval date**
2017-05-24, 1396/03/03

**Ethics committee reference number**
IR.MUMS.fm.REC.1396.43

## Health conditions studied

**1**

**Description of health condition studied**
Functional constipation

**ICD-10 code**
K59.0

**ICD-10 code description**
Constipation

## Primary outcomes

**1**

**Description**
change in stool frequency

**Timepoint**
Every 3 days by pedestrician

**Method of measurement**
questionnaire recording stool frequency changes

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
An ointment containing 85% olive oil is massaged for 5 minutes twice daily on abdominal area for two weeks

**Category**
Treatment - Drugs

**2**

**Description**
An ointment containing 85% liquid paraffin (adjusted to have color and odor similar to those of intervention drug) is massaged for 5 minutes twice daily on abdominal area for two weeks

**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Emam Reza Hospital

**Full name of responsible person**
Hossein Arman Asl

**Street address**

**City**
Mashhad

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Mashhad University of Medical Sciences

**Full name of responsible person**
Dr. Mohsen Tafaghodi

**Street address**
School of pharmacy, Pardis university campus, Park square
**City**
Mashhad
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Mashhad University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
*empty*
**Domestic or foreign origin**
*empty*
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
School of pharmacy, Mashhad University of Medical sciences, Mashhad, Iran
**Full name of responsible person**
Hossein Arman Asl
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Pharm.D. student
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

**Contact**
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Department of Traditional Pharmacy, School of Pharmacy, Mashhad University of Medical sciences, Mash
**Full name of responsible person**
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Assistant professor/ Pharm.D; Ph.D
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## Person responsible for updating data

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Hossein Arman Asl
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*
**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**
*empty*