

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

##### Email address

armanasl911@mums.ac.ir

##### 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 pedestrian

#### 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

**Position**

Pharm.D. student

**Other areas of specialty/work****Street address**

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**City**

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armanaslh@mums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Department of Traditional Pharmacy, School of Pharmacy, Mashhad University of Medical sciences, Mash

**Full name of responsible person**

Behjat Javadi

**Position**

Assistant professor/ Pharm.D; Ph.D

**Other areas of specialty/work****Street address**

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javadib@mums.ac.ir; behjat.javadi@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Hossein Arman Asl

**Position****Other areas of specialty/work****Street address****City****Postal code****Phone**

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**Fax****Email****Web page address****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*