

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### **A comparison between Polyethylene Glycol , Aabdnominal Massage and combination of Poly ethylene glycol with abdominal massage in symptom and quality of life improvement in Functional Constipation.**

#### **Protocol summary**

##### **Study aim**

The efficacy of abdominal massage, Polyethylene Glycol and Combination of Polyethylene Glycol with abdominal massage in symptom relief and quality of life improvement of patients with functional constipation

##### **Design**

This study is not a blinded randomized clinical trial. All patients with chronic functional constipation based on ROM 4 criteria and age 18-65 years who do not have exclusion criteria are randomly assigned in one of the three treatment groups. Each group consists of 44 patients. Group (A) Polyethylene Glycol 20 gr powder(2 sachet of Cololax, Darian Tejarat Company, Iran ) of dissolved in a glass of water, after breakfast ,Once daily . Group (B): Abdominal massage for 15 minutes with Polyethylene glycol 20 gr powder dissolved In a glass of water, after breakfast, Once daily . Group (C): Abdominal massage for 15 minutes daily. Western Abdominal massage therapy will be performed for a period of 2 weeks and will be semi-supervised. The course is performed at least 5 days a week, which is semi-supervised method 2 times a week, by a Physical Medicine and Rehabilitation Specialist and 3 other days of the week will be treated by the same person at home in the same way. Each session will consist of 10 to 15 minutes. In the first visit , after complete explanation for patients, the patients complete the consent form . Demographic data , validated persian version of the Patient Assessment of Constipation Quality of Life questionnaire (PAC-QOL) and stool consistency ( BRISTOL SCORE ) are recorded. After completing a 2-week treatment dration, all patients discontinue the treatment for 2 weeks, and again, the questionnaires will be completed.

##### **Settings and conduct**

This study is not a blinded randomized clinical trial. All patients with chronic functional constipation , who

referred to gastroenterology clinic of Rasoul Akram hospital in 2016-2017( based on ROM4 and whitout any exclusion criteria) are randomly assigned into one of the three treatment groups. Each group consists of 44 patients

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria: Functional constipation based on Rome 4; age 18-65 years Exclusion criteria: History of usage of Opiod , Tricyclic antidepressant, Anti-hypertension, Anti-convulsant, Analgesic, Hypnotic; Systemic disease (Diabetes Melitous, Hypertention, Cardiac , Pulmonary , Renal, liver, Thyroid disease, Cancer, Myopathy, Neuropathy, Sclerodermea); Pregnancy; Breast feeding; Abdominal pain; Irritable Bowel Syndrome; History of Abdominal surgery; Abdominal hernia (Umbilical and /or Inguinal); History of allergy to prescribed medication; Non-compliant and uncooperative; Mechanical and/or Pseudo - intestinal obstruction

##### **Intervention groups**

Group A: Polyethylene Glycol 20 gr powder(2 sachet of Cololax ) that dissolved in a glass of water, after breakfast , Once daily . Group B : Abdominal massage for 15 minutes with Polyethylene Glycol 20 gr powder(2 sachet of Cololax ) dissolved In a glass of water, after breakfast, Once daily . Group C: Abdominal massage for 15 minutes daily

##### **Main outcome variables**

Quality of life and symptoms of patients with functional constipation

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20141201020178N8**

Registration date: **2018-03-02, 1396/12/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-03-02, 1396/12/11**

Update count: **0**

**Registration date**

2018-03-02, 1396/12/11

**Registrant information**

**Name**

Marjan Mokhtare

**Name of organization / entity**

Iran University of Medical sciences,Rasoul Akram Hospital,Colorectal Research Center

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 6652 2845

**Email address**

mokhtare.m@iums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2017-10-14, 1396/07/22

**Expected recruitment end date**

2018-05-12, 1397/02/22

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparison between Polyethylene Glycol , Aabdnominal Massage and combination of Poly ethylene glycol with abdominal massage in symptom and quality of life improvement in Functional Constipation.

**Public title**

Effect of abdominal massage ,Polyethylene Glycol and combined together in symptom and quality of life improvement in Functional Constipation

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with functional constipation based on Rome 4 who have frequently ,2 or more of the following criteria: fewer than 3 defecation per week , hard stool, straining, blockage sensation , sensation of incomplete evacuations, manual maneuvers of evacuation. Age 18-65 years

**Exclusion criteria:**

History of usage of Opiod ,Tricyclic antidepressant, Anti-hypertension, Anti-convulsant, Analgesic, Hypnotic Systemic disease(Diabetes Melitous, Hypertention, Cardiac ,Pulmonary ,Renal,liver,Thyroid disease, Cancer, Myopathy, Neuropathy, Sclerodermea) Pregnancy Breast feeding Abdominal pain Irritable Bowel Syndrome History of Abdominal surgery Abdominal hernia(Umbilical and /or Inguinal) History of allergy to prescribed medication Non-compliant and uncooperative Mechanical

and/or Pseudo - intestinal obstruction

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Care provider
- Data analyser

**Sample size**

Target sample size: **132**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

All patients based on computerized random table ,assigned in one of treatment group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Factorial

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

**Street address**

West Shahid Hemmat Highway, Intersection of Chamran and Sheikh Fazlollah Noori

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2017-10-14, 1396/07/22

**Ethics committee reference number**

IR.IUMS.FMD.REC.1396.26277

**Health conditions studied**

**1**

**Description of health condition studied**

Functional Constipation

**ICD-10 code**

K59.00

**ICD-10 code description**  
Constipation, unspecified

## Primary outcomes

### 1

**Description**

Quality of life in patients with functional constipation and symptom in patients with functional constipation

**Timepoint**

Before Intervention ,2 Weeks after Intervention

**Method of measurement**

Persian version of patient assessment constipation quality of life(PAC-QOL) questionnaire

### 2

**Description**

symptom in patients with functional constipation

**Timepoint**

Before Intervention ,2 and 4 Weeks after Intervention

**Method of measurement**

BRISTOL SCORE

## Secondary outcomes

### 1

**Description**

Patient Compliance Rate

**Timepoint**

Two Weeks after starting treatment

**Method of measurement**

Data gathering sheet

### 2

**Description**

Adverse effects rate

**Timepoint**

Two Weeks after starting treatment

**Method of measurement**

Data gathering sheet

## Intervention groups

### 1

**Description**

Group (A) Treatment with Polyethylene Glycol 20 gr powder(2 sachet of Cololax) of dissolved in a glass of water, after breakfast, Once daily

**Category**

Treatment - Drugs

### 2

**Description**

Group (B): Abdominal massage for 15 minutes with Polyethylene Glycol 20 gr powder(2 sachet of Cololax)of dissolved in a glass of water, after breakfast, Once daily.

**Category**

Treatment - Other

### 3

**Description**

Group (C): Abdominal massage for 15 minutes daily.

**Category**

Treatment - Other

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Colorectal Research Center,Rasoul Akram Hospital

**Full name of responsible person**

Marjan Mokhtare

**Street address**

Niayesh Street ,Sattarkhan Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6655 4790

**Email**

marjanmokhtare@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Seyed Kazem Malakouti

**Street address**

Niayesh Street ,Sattarkhan Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6655 4790

**Email**

kmalakouti@iums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Marjan Mokhtare

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gastroenterology and Hepatology

**Street address**

Niayesh Street ,Sattarkhan Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6655 4790

**Email**

marjanmokhtare@yahoo.com

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

Iran University of Medical Sciences

**Full name of responsible person**

Marjan Mokhtare

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gastroenterology and Hepatology

**Street address**

Colorectal Research Center, Rasoul Akram Hospital,

Niayesh Street, Sattarkhan Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6655 4790

**Fax****Email**

marjanmokhtare@yahoo.com

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

Iran University of Medical Sciences

**Full name of responsible person**

Marjan Mokhtare

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gastroenterology and Hepatology

**Street address**

Colorectal Research Center, Rasoul akram

Hospital, Niayesh Street, Sattarkhan Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6655 4790

**Email**

marjanmokhtare@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**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**

IPD collected for primary outcome

**When the data will become available and for how long**

Starting 6 months after publication

**To whom data/document is available**

People working in academic institutions

**Under which criteria data/document could be used**

Just analyzed data

**From where data/document is obtainable**

Research Administrator of Colorectal Research Center,  
Marjan Mokhtare

**What processes are involved for a request to access**

**data/document**

After applying by email, it will be reviewed and answered.

**Comments**