

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 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

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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 , Aabdnomial 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

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Niayesh Street ,Sattarkhan Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malakouti

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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

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Iran University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Position

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Latest degree

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Other areas of specialty/work

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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