Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparison between Polyethylene Glycol , Aabdominal 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 , Aabdominal 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
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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 Malakooti
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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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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