Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Survey the effect of Anti-Constipation Belt on patients with chronic constipation

Protocol summary

Summary

Survey the effect of Anti-Constipation Belt on patients with chronic constipation Objectives: Abdominal massage is a common and effective treatment to control constipation. Regarding the specific needed method of this treatment, we need a trained and professional operator for that. The main aim of anti-constipation belt designing is removing the operator from this treatment process. Design: This single-blind clinical trial evaluates the therapeutic effects of this device on patients with chronic constipation. Setting and conduct: 30 people in both gender with necessary conditions randomly will be divided in two 15 membered groups: intervention and control. The members of control group will receive osmotic laxatives during this study but in intervention group, the members will be treated by massage with anti-constipation belt in addition to osmotic laxative. Massage therapy is about 8 sessions in average every 3.5 days. Every session will take about 20 minutes. the GSRS (Gastrointestinal Symptoms Rating Scale) questionnaire will be filled For every patient to follow their symptoms improvement in 1st and 4th and 8th visits in both group. In intervention group there is one more questionnaire that will filled in one month after the end of the massage besides to those 3 questionnaires. Major Inclusion and Exclusion criteria: The inclusion criteria will be constipated in accordance with RomeII criteria and dependent on laxatives and exclusion criteria will consisted of known intestinal cancer, recently undergone abdominal surgery, pregnancy and diabetes and etc. Intervention: Massage with Anti-Constipation Belt in patient with chronic constipation Main outcome measures (variables) : The improvement in their symptoms will be based on GSRS questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102719707N1**
Registration date: **2014-11-23, 1393/09/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-11-23, 1393/09/02

Registrant information

Name

Delaram Nahid

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Roshd department, Vice Chancellor for Research, Qazvin University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the effect of Anti-Constipation Belt on patients with chronic constipation

Public title
Effect of Anti-Constipation Belt on patients with chronic constipation
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Constipation in accordance with RomeII criteria; constipation dependent on laxatives. Exclusion criteria: Known intestinal cancer; recently undergone abdominal surgery (6 month ago) ; pregnancy; dementia diagnosis; diabetes; hypothyroidism; cardiovascular and cerebrovascular disease; major depression disorder; abdominal hernia; severe back pain.
Age
From **20 years** old to **80 years** old
Gender
Both

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization method between control and intervention group is based on the time of their 1st visit. It means that in first month, all of the qualified patients categorize in intervention group, then other patients in their 1st visit categorize in control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
Shahid Bahonar Boulevard,
City
Qazvin,
Postal code
Approval date
2014-07-22, 1393/04/31
Ethics committee reference number
28/20/8994

Health conditions studied

1

Description of health condition studied
chronic constipation
ICD-10 code
K92.9
ICD-10 code description
Disease of digestive system, unspecified

Primary outcomes

1

Description
constipation
Timepoint
1st and 4th and 8th visits during the massage session and a month after last session
Method of measurement
GSRS questionnaire (before, during and after of the massage session)

Secondary outcomes

1

Description
Diarrhea
Timepoint
1st and 4th and 8th visits during the massage session and a month after last session
Method of measurement
GSRS questonnaire (before, during and after the massage session)

2

Description
Bloated Abdomen
Timepoint
1st and 4th and 8th visits during the massage session and a month after last session
Method of measurement
GSRS questonnaire (before, during and after the massage session)

3

Description
Gas Passage
Timepoint
1st and 4th and 8th visits during the massage session and a month after last session
Method of measurement
GSRS questonnaire (before, during and after the massage session)

4

Description

Incompelete Defecation

Timepoint

1st and 4th and 8th visits during the massage session and a month after last session

Method of measurement

GSRS questonnaire (before, during and after the massage session)

5

Description

Hard stools defecation

Timepoint

1st and 4th and 8th visits during the massage session and a month after last session

Method of measurement

GSRS questonnaire (before, during and after the massage session)

6

Description

Loose stools defecation

Timepoint

1st and 4th and 8th visits during the massage session and a month after last session

Method of measurement

GSRS questonnaire (before, during and after the massage session)

Intervention groups

1

Description

intervention group, members will be treated by massage with Anti-Constipation belt in addition to osmotic laxative. Massage therapy is about 8 sessions in average every 3.5 days. Every session will take about 20 minutes.The GSRS (gasterointestinal symptoms rating scale) questionnaire will be filled For every patient to follow their symptoms improvement in the 1st and 4th and 8th visits during the massage sessions and one month after the end of the massage.

Category

Treatment - Other

2

Description

members of control group only will receive osmotic laxatives during this study and the GSRS (gasterointestinal symptoms rating scale) questionnaire will be filled for every patient to follow their symptoms improvement in 1st visit and then in 4th week and 8th week.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bouali-sina Hospital

Full name of responsible person

Dr Arash Miroliaee

Street address

Bouali-sina Hospital, Bouali-sina Street,

City

Qazvin,

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Qazvin University of Medical Sciences

Full name of responsible person

Dr. Taghi Naserpour

Street address

Shahid Bahonar Boulevard,

City

Qazvin,

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Arash Miroliaee

Position

Specialist in Gasteroenterology and Hepatology, Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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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