Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative study of the effect of abdominal massage, chewing sugar-free gum and a combined method on the incidence and severity of constipation in patients who have undergone lower limb skeletal traction in Sanandaj in Year 1395

Protocol summary

Summary

This study randomized clinical trial of 124 patients traction skeletal blind in Sanandaj be conducted in Hospital Patients randomly using sealed envelope with re Replacing a laptop into four equal groups: 1.jvydn chewing gum sugar (31), 2.masazh abdomen (31), 3.rvsh combination (n = 31) and 4. The control group (n = 31) will be divided. Patients Group (1) Mark Van chewing sugar-free gum a number 3 times a day for 30 minutes after an hour of eating a meal, patients (2) clockwise abdominal massage for 15 minutes on the clock 9 am and 9 pm with gentle constant pressure, patients groups (3) a combination of chewing gum and abdominal massage to get control Krdnd.grvh receive routine care only.Inclusion criteria: having a pattern of normal bowel movements and constipation prior to the study, skeletal traction approved under the femoral fractures in patients older than 18 years, following the instructions given in the diet based on normal diet, lack of effective underlying disease the bowel movements.Exclusion criteria from the study: lack of desire to continue working, the patient is discharged before 7 days, the use of drugs affecting bowel function such as lactulose, magnesium hydroxide syrup, etc., inability to chew gum.To compare data obtained in the study groups Chi square testAnd also to compare the intensity of constipation based on a rating scale between the groups Mann-Whitney test was used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111730936N1**
Registration date: **2017-01-27, 1395/11/08**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-01-27, 1395/11/08

Registrant information

Name
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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of abdominal massage, chewing sugar-free gum and a combined method on the incidence and severity of constipation in patients who have undergone lower limb skeletal traction in Sanandaj in Year 1395

Public title
The effect of chewing sugar-free gum massage the abdomen and constipation
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:Not having normal bowel movements and constipation model to study femoral fractures in patients older than 18 years approved by skeletal traction Follow the instructions in the diet based on normal diet without affecting the underlying disease bowel movements(Diabetes, depression, hemorrhoids, Fisher, dementia, multiple sclerosis, Parkinson's disease, a history of abdominal surgery, rheumatoid arthritis, hypothyroidism, spinal cord injury).No special diet or weight loss obesity. Lack of skin inflammation or ulcers in the massage area treated with specific drugs affecting the gastrointestinal tract, bowel movements and not (antacids, anticholinergic and anti-Parkinson's medications are, calcium channel blockers, diuretics, iron supplements, anti-inflammatory drugs NSAIDs, and opioid consumption).Lack of inflammatory bowel disease. No smoking and drugs.Exclusion criteria from the study:Not wanting to continue cooperation.Before the patient is discharged 7 days.The use of drugs affecting bowel function such as lactulose, magnesium hydroxide syrup and ...Inability to chew gum
Age
From **18 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **124**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kurdistan University of Medical Sciences
Street address
Kurdistan University of Medical Sciences, after Qods Hospital
City
Sanandaj
Postal code
66177-13446
Approval date
2017-01-16, 1395/10/27
Ethics committee reference number
IR.MUK.REC.1395/282

Health conditions studied

1

Description of health condition studied
constipation
ICD-10 code
K59.0
ICD-10 code description
constipation

Primary outcomes

1

Description
Constipation severity
Timepoint
7 days after the intervention
Method of measurement
questionnaire ROM III

2

Description
The incidence of constipation
Timepoint
7 days after the intervention
Method of measurement
questionnaire ROM III

Secondary outcomes

empty

Intervention groups

1

Description
For patients (3) a combination of chewing sugar-free gum a number Barbd Mark van an hour-a-day eating meals (breakfast, lunch, dinner) for half an hour and massage the abdomen in a clockwise direction for 15 minutes on the clock in the direction transverse colon and descending colon in the left upper abdomen in the direction of the anterior superior iliac spine down the left Without prejudice to patient privacy for 7 days + care routine will be performed by the principal investigator.
Category
Prevention

2

Description
To control (4) routine actions, such as recommendations to increase fluid intake, fiber intake, and active and passive movements in bed is recommended.

Category
Prevention

3

Description
For patients (2) clockwise abdominal massage for 15 minutes per hour of 9 am and 9 pm with gentle constant pressure with two or three fingers in a clockwise direction to rotate the area of the anterior superior iliac spine straight day + care routine will be performed by the principal investigator.

Category
Prevention

4

Description
For patients (1) chewing sugar-free gum a number Mark van (25-gram package containing xylitol) 3 times a day for 30 minutes after an hour of eating every meal + routine hospital for 7 days prescribed by Research Associate and monitored.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Hospital Besat

Full name of responsible person
aram nezakati

Street address
Besat Hospital, Keshavarz Street, Sanandaj

City
sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research and technology of Kurdistan University of Medical Sciences

Full name of responsible person
Farzin Rezaee

Street address
Vice Chancellor for research and technology of Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj

City
Sanandaj

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 and technology of Kurdistan 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
Kurdistan University of medical sciences

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aram nezakati

Position
Nurse/MS.C

Other areas of specialty/work

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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