Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of a short-term walking after meals versus the use of prokinetic medications in improving gastrointestinal symptoms in individuals with functional abdominal bloating: a randomized clinical trial

Protocol summary

Study aim
The present study aims to compare the effect of a short duration postprandial walking and prokinetic medications on bloating reported by healthy individuals.
Design
Two arm parallel group randomized trial
Settings and conduct
The work is a clinic-based study and study duration is 4 weeks.
Participants/Inclusion and exclusion criteria
Patients aged between 15-75 years old who were diagnosed to have functional abdominal bloating with Rome IV criteria were included in the study. Patients with alarming points in medical history, symptoms, physical examination and laboratory data were excluded from the study.
Intervention groups
1. In control group, individuals were given daily domperidone plus activated dimethicone as a prokinetic medication. 2. In intervention group, the subjects were asked to perform a particular exercise after each meal. This exercise consists of 10-15 minutes of slow walking (reaching 1000 steps) walking with hand clasped together behind the body and flexed neck (around 45 degree) posture.
Main outcome variables
1. Postprandial epigastric fullness/bloating 2. Belching 3. Flatus 4. Abdominal discomfort/pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200310046739N1**
Registration date: **2021-01-14, 1399/10/25**
Registration timing: **retrospective**

Last update: **2021-01-14, 1399/10/25**
Update count: **0**
Registration date
2021-01-14, 1399/10/25

Registrant information
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Erfan Taherifard
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-01, 1396/10/11
Expected recruitment end date
2020-02-01, 1398/11/12
Actual recruitment start date
2018-02-03, 1396/11/14
Actual recruitment end date
2020-03-01, 1398/12/11
Trial completion date
2020-04-05, 1399/01/17

Scientific title
Comparison of the effectiveness of a short-term walking after meals versus the use of prokinetic medications in improving gastrointestinal symptoms in individuals with functional abdominal bloating: a randomized clinical trial

Public title
Effect of a short-term walking after meals in improving gastrointestinal symptoms in individuals with functional abdominal bloating
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who meet the Rome IV criteria as diagnostic criteria for functional bloating/distension are included in the study
Exclusion criteria:
Patients with history of anorexia, weight loss, alteration in bowel habit, chronic diarrhea and upper/lower gastrointestinal bleeding over the past 3 months are excluded from the study Patients with alarming points in physical examination including jaundice, organomegaly, ascites and temporal wasting are excluded Individuals are not included in the study if they had any abnormal laboratory workup indicating an underlying disorder, body mass index ≥40, a history of GI or abdominopelvic surgery or significant coexisting medical condition or medications that affect GI tract motility Furthermore, those subjects that were pregnant are excluded from the study
Age
From **15 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The process of randomization and allocation will be performed by an independent external researcher. The participants are randomized into two groups of intervention and control with the allocation rate of 1:1. The randomization process will be provided by a web-based randomization application (https://app.studyrandomizer.com/) which which generated a simple randomization sequence.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Research and technology department, Administration Building of Shiraz University of Medical Sciences Zand St.
City
Shiraz
Province
Fars
Postal code
۷۱۳۴۸۱۴۳۳۶
Approval date
2020-09-01, 1399/06/11
Ethics committee reference number
IR.SUMS.MED.REC.1399.315

Health conditions studied

1

Description of health condition studied
Functional Abdominal Bloating
ICD-10 code
R14.0
ICD-10 code description
Abdominal distension (gaseous)

Primary outcomes

1

Description
Belching
Timepoint
Before intervention and 4 weeks after study intervention
Method of measurement
Using a 5-point Likert scale (1=very mild, 2=mild, 3=moderate, 4=severe, 5=very severe)

2

Description
Postprandial epigastric fullness/bloating
Timepoint
Before intervention and 4 weeks after study intervention
Method of measurement
Using a 5-point Likert scale (1=very mild, 2=mild, 3=moderate, 4=severe, 5=very severe)

3

Description
Abdominal discomfort/pain
Timepoint
Before intervention and 4 weeks after study intervention

Method of measurement
Using a 5-point Likert scale (1=very mild, 2=mild, 3=moderate, 4=severe, 5=very severe)

4

Description
Flatus
Timepoint
Before intervention and 4 weeks after study intervention
Method of measurement
Using a 5-point Likert scale (1=very mild, 2=mild, 3=moderate, 4=severe, 5=very severe)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The subjects in the intervention group were asked to perform a particular exercise after each meal. All the intervention group participants had to install Pedometer Step Counter application on their smartphones (https://play.google.com/store/apps/details?Id=pedometer.steptracker.calorieburner.stepcounter&hl=en). This exercise consists of 10-15 minutes of slow walking (reaching 1000 steps), walking with hand clasped together behind the body and flexed neck (around 45 degree) posture without talking meanwhile.
Category
Treatment - Other

2

Description
Control group: Individuals were given daily domperidone plus activated dimethicone as a prokinetic medication(10 mg, 30 mins before lunch and dinner)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari Clinic
Full name of responsible person
Mohammad Kazem Hosseiniasl
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Motahari clinic, Karim Khan Zand Blvd.
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Sponsors / Funding sources

1

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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Erfan Taherifard
Position
دانشجوی دوره عمومی
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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