Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

The effect of cupping in patients with functional bloating

Protocol summary

Study aim
Determining the effect of cupping therapy in patients with functional bloating

Design
Two parallel group randomized trial with a table of random numbers

Settings and conduct
Patients with bloating referred to a specialized gastroenterology clinic, who meet the inclusion criteria, with the approval of a gastroenterologist, are entered into the study. According to the statistical consultant, patients are randomly placed in one of the two research groups based on the table of random numbers. The first group receives 40 mg dimethicone capsules every 8 hours for two weeks, and the second group is cupped twice a week for two weeks, with dimethicone 40 mg capsules every 8 hours for two weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: all patients aged 18 to 55 years who have symptoms of bloating and have both of the following two criteria according to ROME 4: 1- Feeling of frequent bloating, sense of fullness, or increased abdominal distention, that these symptoms occur at least 1 day a week and overcome other symptoms. 2- The onset of symptoms should be at least 6 months before the diagnosis and the predominant symptoms (bloating or distention) have been present for the past 3 months. Exclusion criteria: 1. Pregnancy or breastfeeding in women 2. Acute or chronic diseases of the gastrointestinal tract 3. Celiac disease 4. functional dyspepsia 5. irritable bowel syndrome

Intervention groups
Interventional group1: Dimethicone capsule consisted of 40mg Dimethicone, three times a day (TID), 2 weeks
Interventional group2: abdominal cupping therapy with the use of 40mg Dimethicone, TID, 2 weeks

Main outcome variables
Severity of bloating; frequency of bloating

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200925048832N1**
Registration date: **2020-10-22, 1399/08/01**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-22, 1399/08/01**
Update count: **0**

Registration date
2020-10-22, 1399/08/01

Registrant information
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Mohammad Saeed Kalantari Meybodi
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-10-06, 1399/07/15
Expected recruitment end date
2020-12-05, 1399/09/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of cupping in patients with functional bloating

Public title
The effect of cupping in functional bloating
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients aged 18 to 55 years who have symptoms of bloating and have both of the following two criteria according to ROME 4. 1. Feeling of frequent bloating, sense of fullness, or increased abdominal distention, that these symptoms occur at least 1 day a week and overcome other symptoms. 2. The onset of symptoms should be at least 6 months before the diagnosis and the predominant symptoms (bloating or distention) have been present for the past 3 months.
Exclusion criteria:
Pregnancy or breastfeeding in women Acute or chronic diseases of the gastrointestinal tract Celiac disease functional dyspepsia irritable bowel syndrome
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Before sampling, using the table of random numbers, which will be given two numbers 1 and 2, and number 1 as the control group and number 2 as the intervention group, and the samples in the order of the numbers given by this software, they will be placed in groups.
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 Yazd Shahid Sadoughi University of Medical Sciences
Street address
Ethics committee of Yazd University of Medical Sciences, Bahonar Square, Yazd
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Yazd
Province
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Postal code
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Approval date
2020-06-23, 1399/04/03
Ethics committee reference number
IR.SSU.REC.1399.073

Health conditions studied

1

Description of health condition studied
Bloating
ICD-10 code
R14
ICD-10 code description
Flatulence and related conditions

Primary outcomes

1

Description
severity of bloating
Timepoint
Before the study, two weeks after starting the study, and two weeks after finishing the study.
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Frequency of bloating
Timepoint
Before the study, two weeks after starting the study, and two weeks after finishing the study.
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group: Cupping therapy will be performed four times. Each cupping therapy session time will be about 10-15 minutes. The intervention time will be fourteen days, and every three days a cupping therapy will take place. This group will also receive 40 mg dimethicone tablets made by Amin Company three times a day for two weeks.
Category
Treatment - Other

2

Description
Control group: This group receives 40 mg dimethicone tablets made by Amin Company every 8 hours for two weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Meybod hospital
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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
Yazd 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
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PhD student
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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