

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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

Name

Mohammad Saeed Kalantari Meybodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3223 8916

Email address

saeedkalantari@ssu.ac.ir

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

City

Yazd

Province

Yazd

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

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mohammad Saeed Kalantari Meybodi

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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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