

# 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**

۸۹۱۶۹۷۸۴۷۷

**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

Mohammad Saeed Kalantari Meybodi

##### Street address

Basij Blvd

##### City

Meybod

##### Province

Yazd

##### Postal code

8961978143

##### Phone

+98 35 3235 1200

##### Fax

+98 35 3235 4025

##### Email

saeed7md@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Ardakan hospital

##### Full name of responsible person

Mohammad Saeed Kalantari Meybodi

##### Street address

Resalat Blvd

##### City

Ardakan

##### Province

Yazd

##### Postal code

8951859931

##### Phone

+98 35 3222 2115

##### Email

ziaee\_hospital@ssu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Masoud Mirzaee

#### Street address

Bahonar Square

#### City

Yazd

#### Province

Yazd

#### Postal code

۸۹۱۶۹۷۸۴۷۷

#### Phone

+98 35 3724 0171

#### Email

dvc.research@ssu.ac.ir

#### 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

##### Street address

No.22, Shahriar Ave, Imam sadegh Town

##### City

Meybod

##### Province

Yazd

##### Postal code

8961978143

##### Phone

+98 35 3235 4025

##### Fax

##### Email

saeedkalantari@ssu.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Razieh Nabi Meybodi  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Traditional Medicine  
**Street address**  
Bahonar Square  
**City**  
Yazd  
**Province**  
Yazd  
**Postal code**  
۸۹۱۶۹۷۸۴۷۷  
**Phone**  
+98 35 3724 0171  
**Email**  
r.nabimeybodi@gmail.com

## Person responsible for updating data

### 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

**Street address**  
No.22, Shahriar Ave, Imam sadegh Town  
**City**  
Meybod  
**Province**  
Yazd  
**Postal code**  
8961978143  
**Phone**  
+98 35 3235 4025  
**Fax**  
**Email**  
saeedkalantari@ssu.ac.ir

## 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