

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Chamomile Efficacy in relief of symptoms of Irritable Bowel Syndrome in Patients with Irritable Bowel Syndrome

Protocol summary

Summary

We decide to treat IBS symptoms with chamomile. In a randomized clinical trial, 45 patients who fulfilled the ROOM II criteria and had no organic disease enrolled in this study and were asked to take Chamomile 20 drops daily for four weeks. Exclusion criteria: history of sensitivity to milk and its products, other active illnesses. They were asked to fill in IBS-associated symptoms questionnaire to specify abdominal pain intensity, bloating, nausea, stool consistency and altered bowel habits. The questionnaire was filled out during 5 visits: at the first day, at the second and fourth weeks after starting the treatment and also the second and fourth weeks after the end of intervention. We expect that symptoms must be better or relief totally.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106206842N1**

Registration date: **2012-06-27, 1391/04/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-06-27, 1391/04/07

Registrant information

Name

Shahram Agah

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2009-09-28, 1388/07/06

Expected recruitment end date

2010-10-17, 1389/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Chamomile Efficacy in relief of symptoms of Irritable Bowel Syndrome in Patients with Irritable Bowel Syndrome

Public title

Chamomile Efficacy in Irritable Bowel Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of IBS (with diarrhea or constipation dominance); no history of sensitivity to milk and its products, age between 10 to 50 years; willingness to participate; no other active illness (especially asthma); no drug consumption (especially anticoagulants); no psychiatric illness; not having pregnancy or doing breast feeding; no history of hyper sensitivity; no current therapy for IBS; and no abnormal lab data (CBC/ ESR/ CRP/ TSH). Exclusion criteria: history of sensitivity to milk and its products; other active illnesses (especially asthma); any psychiatric illnesses; history of hypersensitivity; current therapy for IBS; any abnormal lab data (CBC/ESR/CRP/TSH)

Age

From **10 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethic committee of Medical School of Tehran
University of Medical sciences

Street address

Tehran University of Medical Science- Hemmat
highway,next to Milad Hospital

City

Tehran

Postal code

Approval date

2010-12-21, 1389/09/30

Ethics committee reference number

896/5

Health conditions studied

1

Description of health condition studied

irritable bowel syndrome

ICD-10 code

K58.0, K58

ICD-10 code description

Irritable bowel syndrome with diarrhoea, Irritable bowel
syndrome without diarrhea

Primary outcomes

1

Description

frequency of bowel habit

Timepoint

every two weeks

Method of measurement

questionare

2

Description

abdominal pain

Timepoint

every two weeks

Method of measurement

questionare

Secondary outcomes

1

Description

distention

Timepoint

every two weeks

Method of measurement

questionare

Intervention groups

1

Description

45 patients who fulfilled the ROOM II criteria and had no organic disease enrolled in this study and were asked to take Chamomile 20 drops daily for four weeks. They were asked to fill in IBS-associated symptoms questionnaire to specify abdominal pain intensity, bloating, nausea, stool consistency and altered bowel habits

Category

Treatment - Other

2

Description

a prospective pre-post study in camomile use The drop was produced by Soha Jissa Company Tehran, Iran and contained bizabulol and camazolen (69.47 mg/100cc). The patients used the drop for 4 weeks, 10 drops each 12 hours, 15 minutes after meal. They had to solve it in warm water.

Category

Treatment - Drugs

3

Description

This intervention dont have any control group. This study is a comparing method between before and after camomile use in patients who use camomile.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoolakram Hospital

Full name of responsible person

Dr Shahram Agah

Street address

Shahrara; Nyayesh Ave.; Sattarkhan Str.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Shahin Akhoondzadeh

Street address

Central Department of Tehran University Of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences, Medical School

Full name of responsible person

dr Reyhaneh Asadi

Position

research assistant in research faculty of medical sciences, general practitionare

Other areas of specialty/work

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Person responsible for scientific inquiries

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shahram agah

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Person responsible for updating data

Contact

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Position

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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