Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 camomile. 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 dominancy); no history of sensitivity to milk and its products, age between 10 to 50 years; willingness to participate; no other active illness (specially asthma); no drug consumption (specially 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(specially 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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gastroenterologist

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Person responsible for updating data

Contact

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Other areas of specialty/work

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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