Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

A clinical trial to comparison the effectiveness of aromatherapy inhaler of rose essence with placebo (grape seed Oil) in clinical outcomes of irritable bowel syndrome (IBS) patients.

Protocol summary

Summary

Objective: To comparison the effectiveness of aromatherapy inhaler of rose essence with placebo (grape seed Oil) in clinical outcomes of irritable bowel syndrome (IBS) patients. Design: A double-blind block randomized clinical trial. Study population: Irritable bowel syndrome (IBS) patients. Inclusion criteria: Aged between 15 and 60 years; Abdominal pain or discomfort at least three days a month in the past three months; patients with mild-to-moderate IBS; Lack of nasal polyps (NP) or deviated nasal septum (DNS) disease; Having cranial nerve activity with examination; Lack of specific psychiatric diagnoses which led him to be hospitalized. Exclusion criteria: Failure to use the correct fragrance; Drugs, tobacco or hookah addiction; Allergic reaction to essential oils; Using complementary or alternative medicine; Having allergic rhinitis and respiratory diseases. Sample size: 60 cases. Study intervention: The control group are revising placebo (grape seed Oil) and intervention group are revising rose essence nose against on non-absorbable paper for 20 minutes twice a day for 4 weeks. Study outcome: Comparison of the CT scan with urinalysis for better diagnosis of kidney injury in abdominal blunt trauma patients. Study outcome: Evaluation and comparison of clinical outcomes including pain frequency, pain duration, poop's consistency, defecation frequency, etc. in intervention and control groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016123031663N1**
Registration date: **2017-02-14, 1395/11/26**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2017-02-14, 1395/11/26

Registrant information

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Mashhad University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to comparison the effectiveness of aromatherapy inhaler of rose essence with placebo (grape seed Oil) in clinical outcomes of irritable bowel syndrome (IBS) patients.

Public title
The effectiveness of aromatherapy inhaler on irritable bowel syndrome (IBS) patients.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Aged between 15 and 60 years; Abdominal pain or discomfort at least three days a month in the past three months; patients with mild-to-moderate IBS; Lack of nasal polyps (NP) or deviated nasal septum (DNS) disease; Having cranial nerve activity with examination; Lack of specific psychiatric diagnoses which led him to be hospitalized. Exclusion criteria: Failure to use the correct fragrance; Drugs, tobacco or hookah addiction; Allergic reaction to essential oils; Using complementary or alternative medicine; Having allergic rhinitis and respiratory diseases.
Age
From **15 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
City
Mashhad
Postal code
Approval date
2016-07-22, 1395/05/01
Ethics committee reference number
IR.MUMS.fm.REC.1395.389

Health conditions studied

1

Description of health condition studied
Irritable bowel syndrome
ICD-10 code
K58
ICD-10 code description
Irritable bowel syndrome

Primary outcomes

1

Description
Clinical outcomes including pain frequency, pain duration, poop's consistency, defecation frequency, etc.
Timepoint
4 weeks after intervention
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Irritable bowel syndrome (IBS) patients are revising placebo (grape seed Oil) nose against on non-absorbable paper for 20 minutes twice a day for 4 weeks and evaluation of clinical outcomes of patients
Category
Treatment - Drugs

2

Description
Interventional group: Irritable bowel syndrome (IBS) patients are revising rose essence nose against on non-absorbable paper for 20 minutes twice a day for 4 weeks and evaluation of clinical outcomes of patients.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Mahtab Rashidpour
Street address
Ghaem Hospital, Ahmadabad Avenue

City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
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Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Mashhad 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
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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