Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the effects of mint and cuminum extract on residual volume and abdominal distention in patients under mechanical ventilation

Protocol summary

Study aim
Comparing the effects of mint and cuminum extract on residual volume and abdominal distention in patients under mechanical ventilation

Design
A randomized clinical trial with 3 groups(peppermint, cuminum and control), without blinding, phase II, conducted on 114 patients. Randomization will be performed using sequentially numbered, sealed envelopes.

Settings and conduct
This study will be conducted on mechanically ventilated patients in Ghaem and Imam Reza hospitals in Mashhad. Eligible patients will be enrolled in the study after assessment of the inclusion criteria and obtaining informed consent from the patient or their legal representative. participants will be randomly assigned to 3 groups: peppermint, cuminum and control groups. The intervention groups will receive peppermint or cuminum extract according to the study protocol, and the control group will receive routine care of the ward. GRV and abdominal distention will be measured and recorded at the predetermined times according to the study protocol.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Under mechanical ventilation, Age18 years or older, At least24 hours have passed since admission, Hemodynamically stable, Receiving enteral nutrition via NGT, Informed consent from the patient or their legal representative; Exclusion criteria: allergy to peppermint or cuminum, pregnant or breastfeeding, hypothyroidism, active GI bleeding or peptic ulcer, gallstone or liver failure

Intervention groups
In this study, there will be 3 groups: peppermint, cuminum and control groups. The peppermint group will receive peppermint extract according to the study protocol, the cuminum group will receive cuminum extract according to the study protocol. The control group will receive routine care of the ward and will not receive the herbal intervention.

Main outcome variables
Gastric residual volume; abdominal distention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260617069846N1**
Registration date: **2026-06-28, 1405/04/07**
Registration timing: **prospective**

Last update: **2026-06-28, 1405/04/07**
Update count: **0**

Registration date
2026-06-28, 1405/04/07

Registrant information

Name
Helia Gerami Moghadam

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-07-01, 1405/04/10

Expected recruitment end date
2026-11-21, 1405/08/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of mint and cuminum extract on residual volume and abdominal distention in patients under mechanical ventilation

Public title

Evaluating the effects of peppermint and cumin extract on gastric residual volume and abdominal distension in mechanically ventilated patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Be under mechanical ventilation Be aged 18years or older At least 24 hours have elapsed since admission Be hemodynamically stable Receiving enteral nutrition via NGT The patient or their legal representative provides informed consent

Exclusion criteria:

The patient has an allergy to peppermint or cumin The patient is pregnant or breastfeeding The patient has GI Bleeding or peptic ulcer disease The patient has gallstone or liver failure

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

A random allocation sequence will be generated using randomization software. Allocation codes will be placed in sequentially numbered, opaque, sealed envelopes. After each eligible patient is enrolled, the next envelope in numerical order will be opened, and the patient will be assigned to one of the three study groups: peppermint, cumin, or control.

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 Mashhad University of Medical Sciences

Street address

4th Floor, Shahid Dr.Kharazmi Educational Complex, University Campus, Eastern Gate of Ferdowsi University of Mashhad, Azadi Square.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2026-06-02, 1405/03/12

Ethics committee reference number

IR.MUMS.NURSE.REC.1405.029

Health conditions studied

1

Description of health condition studied

Under mechanical ventilated patients

ICD-10 code

Z99.1

ICD-10 code description

Dependence on respirator

Primary outcomes

1

Description

Gastric residual volume

Timepoint

Measurements will be performed immediately before and 3 hours after gavage administration of the respective extract at12,18, and24 hours.

Method of measurement

It will be measured using 50cc syringe.

2

Description

Abdominal distention

Timepoint

Measurements will be performed immediately before and 3 hours after gavage administration of the respective extract at12,18, and24 hours.

Method of measurement

Measurements will be performed using measuring tape (with an accuracy of 0.5 cm) before and 3 hours after gavage administration of the study extracts (at 12, 18,and 24).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Patients in this group will receive peppermint extract manufactured by Barij Essence Pharmaceutical Company. This product contains the main active constituents of peppermint, including menthol and menthone. This intervention will be administered as 20 drops of peppermint extract diluted in 30cc of drinking water via a NGT at 9, 15 ,21. The duration of the intervention will be 24 hours. Intervention group2: Patients in this group will receive Cuminum cyminum extract manufactured by Barij Essence Pharmaceutical Company. This product contains the main active constituents of cumin, including cuminaldehyde and other volatile compounds. This intervention will be administered as 20 drops of cumin extract diluted in 30cc of drinking water via a NGT at 9, 15 ,21. The duration of the intervention will be 24 hours.

Category

Treatment - Drugs

2

Description

Control group: Patient in this group will receive routine ward care and will not receive any herbal intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem hospital of Mashhad

Full name of responsible person
Mahmood Bakhshi

Street address
Ghaem(AJ) Educational, Research and treatment Center, Ahmadabad Street, Dr.Shariati(Taghiabad) Square.

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4578591871

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2

Recruitment center

Name of recruitment center
Imam Reza hospital of Mashhad

Full name of responsible person
Mahmood Bakhshi

Street address
Imam Reza Hospital, Imam Reza Square, Ibn Sina Street.

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1331691379

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

Street address
4th Floor, Research Deputy Office, Shahid Dr.Kharazmi Educational Complex, University Campus, Eastern Gate of Ferdowsi University of Mashhad, Azadi Square.

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nms.pr@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Mahmood Bakhshi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Shahid Dr. Kharazmi Educational Complex, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Mahmood Bakhshi

Position
Associate professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person
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Latest degree
Ph.D.

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Protection of Privacy

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Study protocol of the clinical trial including objectives, methodology, interventions, outcomes, and statistical analysis plan.

When the data will become available and for how long
The study protocol will be available from the time of trial registration and throughout the study period.

To whom data/document is available
Researchers, peer reviewers, ethic committees, and other authorized individuals.

Under which criteria data/document could be used
For research transparency, methodology assessment, and scientific use with appropriate citation.

From where data/document is obtainable
Requests for access to the study protocol should be directed to Dr. Mahmood Bakhshi, Head of the Medical_Surgical Nursing Department, School of Nursing and Midwifery, Mashhad University of Medical Sciences, and the principal supervisor of the study, through Mashhad University of Medical Sciences.(mail:

Bakhshim@mums.ac.ir)

What processes are involved for a request to access data/document

Requests should be submitted in writing or by email to the principal investigator. The request will be reviewed in terms of its intended purpose and its compliance with scientific and ethical considerations. Upon approval by the principal investigator and the study's primary supervisor, the study protocol will be made available to the applicant via email or other official means.

Comments