

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Oral Drop Mentha spicata (Spearmint) on Gastric Residual Volume in Mechanically Ventilated Patients Hospitalized in the Intensive Care Unit

Protocol summary

Study aim

Determination of Oral Drop Mentha spicata (Spearmint) effect on Gastric Residual Volume in Mechanically Ventilated Patients Hospitalized in the Intensive Care Unit

Design

A randomized, triple blinded, controlled trial with parallel groups

Settings and conduct

The study is a randomized, triple blinded, parallel-group controlled trial that is performed at Bohlul Hospital in Gonabad, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients under mechanical ventilation with >24 hours stay in the intensive care unit (ICU), ages between 18 to 65 years old, informed consent of parents or legal guardian
Non-inclusion criteria: Having gallstones, history of active gastrointestinal bleeding, malignancies, gastrointestinal ulcer, diabetes and pancreatitis, Pregnancy and breastfeeding, history of Hypothyroidism according to the statement of people accompanying the patient, Oral nutrition or use of a duodenal catheter

Intervention groups

Patients in the intervention group receive 20 drops of the Spearmint solution along with 40 ml of water, 3 times daily for 4 days, from the first day of their feeding. The control group patients receive 20 drops of placebo along with 40 ml of water.

Main outcome variables

Gastric residual volume

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191223045868N1**

Registration date: **2020-03-28, 1399/01/09**

Registration timing: **prospective**

Last update: **2020-03-28, 1399/01/09**

Update count: **0**

Registration date

2020-03-28, 1399/01/09

Registrant information

Name

Fatemeh Mohammadzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 5213

Email address

f.mo6325@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Oral Drop Mentha spicata (Spearmint) on Gastric Residual Volume in Mechanically Ventilated Patients Hospitalized in the Intensive Care Unit

Public title

Effect of Oral Drop Mentha spicata (Supermint) on Gastric Residual Volume in Mechanically Ventilated Patients Hospitalized in the Intensive Care Unit

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients under mechanical ventilation with >24 hours stay in the intensive care unit (ICU) Ages between 18 to 65 years old Informed consent of parents or legal guardian

Exclusion criteria:

Having gallstones History of active gastrointestinal bleeding, malignancies, gastrointestinal ulcer, diabetes and pancreatitis Pregnancy and breastfeeding History of Hypothyroidism according to the statement of people accompanying the patient Oral nutrition or use of a duodenal catheter

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: Permuted block randomization with a fixed block size of 4 Unit of randomization: Individual Tools used in randomization: sealed envelopes, computer software How the random sequence is built: Random allocation software How allocation concealment is carried out: Sequentially numbered, sealed, opaque envelopes

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients in both groups are unaware of the treatment being used. The intervention and the assessment of the result are performed by two different individuals, and so the result assessor will not be informed of the form of treatment being allocated. For the gavage material, A and B codes are considered, and the data analyzer is not told the type of gavage material.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Asian Road Border

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2020-02-25, 1398/12/06

Ethics committee reference number

IR.GMU.REC.1398.187

Health conditions studied

1

Description of health condition studied

Gastric Residual Volume

ICD-10 code

K31.9

ICD-10 code description

Disease of stomach and duodenum, unspecified

Primary outcomes

1

Description

Gastric Residual Volume

Timepoint

Before each gavage during the study

Method of measurement

By aspirating the stomach contents with a 60 ml syringe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group receive 20 drops of the Supermint solution along with 40 ml of water, 3 times daily for 4 days, from the first day of their feeding.

Category

Prevention

2

Description

Control group: Patients in the control group receive 20 drops of the placebo along with 40 ml of water, 3 times daily for 4 days, from the first day of their feeding.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Bohlul Hospital in Gonabad

Full name of responsible person

Ali Delshad Noghabi

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Gonabad University of Medical Sciences, Asian Road
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Shahla Khosravan

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mmakhosravan@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Ali Delshad Noghabi

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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