# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

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

### Protocol summary


**Study aim**
Determination of Oral Drop Mentha spicata (Supermint) 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 Supermint 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**

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Iran (Islamic Republic of)

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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 (Supermint) 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 envelops, 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 plasebo 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
**Street address**
Gonabad University of Medical Sciences, Asian Road Border
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ali_delshad2000@yahoo.com

## 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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**Latest degree**

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**Other areas of specialty/work**

Nursery

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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