

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Apr 2022

### Effect of peppermint essential oil Oral Drop (*Mentha spicata*) or 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 18 years and older, 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

###### 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* (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 years and older 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

18 years and older

## 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

**Street address**

Gonabad University of Medical Sciences, Asian Road  
Border

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

9691793718

**Phone**

+98 51 5722 3028

**Email**

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

**Street address**

Gonabad University of Medical Sciences, Asian Road  
Border

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

9691793718

**Phone**

+98 51 5722 3028

**Email**

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 updating data

**Contact**

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Gonabad University of Medical Sciences

**Full name of responsible person**

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**Latest degree**

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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