

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the effect of Mint and Chamomile on residual stomach volume in patients undergoing nasogastric feeding in intensive care unit, Kowsar hospital, Semnan

Protocol summary

Study aim

The aim of this study is to compare the effect of mint and chamomile on gastric residual volume in patients who admitted in intensive care units and feed via nasogastric tube.

Design

In a clinical trial, patients were assigned to study groups using randomized six-block. The person who evaluated outcomes was not aware from the type of intervention.

Settings and conduct

The study was conducted at Kowsar Hospital affiliated with the Semnan University of Medical Sciences and Health Services.

Participants/Inclusion and exclusion criteria

The research sample is all patients undergoing feeding by nasogastric tube who be admitted to the intensive care unit for more than 24 hours and ventilated mechanically with supportive modes, will be enrolled in the study. Patients who are hospitalized for gastrointestinal surgery, patients who has food allergy and vomiting, as well as pregnant and breastfeeding women and patients with diabetes are excluded from the study.

Intervention groups

First group will receive 5 milliliter of peppermint solution via nasogastric tube after each feeding period during 24 hours in addition to the usual management. After 12 hours from the last feeding and receiving of peppermint solution, in the next 24 hours, at the end of each feeding period, 8 ml of chamomile solution is given via nasogastric tube. Second intervention group, will receive of chamomile solution via nasogastric tube after each feeding period during 24 hours. After 12 hours from the last feeding and receiving of chamomile solution, in the next 24 hours, 5 milliliter of peppermint solution is given to the patient via nasogastric tube. Before each gavage, gastric residual is measured by aspiration, if gastric

residual volume is less than 50% of the intake returned to the patient.

Main outcome variables

Main outcome variable is Gastric residual volume

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151020024625N10**

Registration date: **2019-02-06, 1397/11/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-06, 1397/11/17**

Update count: **0**

Registration date

2019-02-06, 1397/11/17

Registrant information

Name

Mehrdad Zahmatkesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3343 7844

Email address

mehrdadzahmatkesh@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2019-06-09, 1398/03/19

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Mint and Chamomile on residual stomach volume in patients undergoing nasogastric feeding in intensive care unit, Kowsar hospital, Semnan

Public title
Comparison of The effect of Mint and Chamomile on residual gastric volume in patients undergoing nasogastric feeding

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Admission to ICU for more than 24 hours Feeding via nasogastric tube
Exclusion criteria:
Admission to ICU due to gastrointestinal surgery

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization by six block randomization

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patient, person who collected data and analyzed will be blinded of the type of intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address
Basidj Boulevard

City
Semnan

Province
Semnan

Postal code
3519899951

Approval date
2019-01-06, 1397/10/16

Ethics committee reference number
IR.SEMUMS.REC.1397.219

Health conditions studied

1

Description of health condition studied

Gastric residual volume

ICD-10 code

K30

ICD-10 code description

Delayed gastric emptying

Primary outcomes

1

Description

Gastric residual volume

Timepoint

Every 3 hours at the end of the nutrient solution gavage

Method of measurement

By NG tube and aspiration with syringe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First intervention group, in addition to the usual management and interventions, will receive 5 milliliter of peppermint solution (40 drops peppermint extract in 40 ml of drinking water) through the nasogastric tube after each feeding period during 24 hours. After 12 hours from the last feeding and receiving of peppermint solution, in the next 24 hours, at the end of each feeding period, 8 ml of chamomile solution (90 drops of chamomile in 40 milliliter of drinking water) is given to the patient through the nasogastric tube. Before each feeding, the gastric residual is measured by aspiration and recorded, if gastric residual volume is less than 50% of the intake returned to the patient.

Category

Treatment - Other

2

Description

Intervention group: Second intervention group, in addition to the usual management and interventions, will receive of chamomile solution (90 drops of chamomile in 40 milliliter of drinking water) through the nasogastric tube after each feeding period during 24 hours. After 12 hours from the last feeding and receiving of chamomile solution, in the next 24 hours, at the end of each feeding period, 5 milliliter of peppermint solution (40 drops peppermint extract in 40 ml of drinking water) is given to the patient through the nasogastric tube. Before each feeding, the gastric residual is measured by aspiration and recorded, if gastric residual volume is less than 50% of the intake returned to the patient.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital, affiliated to Semnan Universities of Medical Sciences

Full name of responsible person

Samaneh Rahbar

Street address

Basidj Boulevard

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3142 2120

Email

bahar.samaneh.89@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei MD

Street address

Basidj Boulevard

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3345 1336

Email

sem.ums.res@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Abassali Ebrahimi PhD

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health in Emergency and Disaster

Street address

Km 5 Dameghan Road, Nursing Faculty

City

Semnan

Province

Semnan

Postal code

3513138111

Phone

+98 23 3346 5191

Email

aa.ebrahimi@semums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Abassali Ebrahimi PhD

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health in Emergency and Disaster

Street address

Basidj Boulevard

City

Semnan

Province

Semnan

Postal code

3513138111

Phone

+98 23 3346 5191

Email

aa.ebrahimian@semums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Mehrdad Zahmatkesh

Position

Researcher

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Km 5 Dameghan Road, Nursing Faculty

City

Semnan

Province

Semnan

Postal code

3513138111

Phone

+98 23 3346 5191

Email

mehrdadzahmatkesh@semums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only final report will be published.

When the data will become available and for how long

After completing of study

To whom data/document is available

Any person who request.

Under which criteria data/document could be used

Referees

From where data/document is obtainable

Contact by email

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

Contact with responsible person and supervisor permission

Comments