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 Ebrahimian 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.ebrahimian@semums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Abassali Ebrahimian 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 repot will 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