Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Determining the effect of not measuring the gastric residual volume on the success rate in achieving the target calorie of enteral nutrition in patients with endotracheal tubes hospitalized in the intensive care units of Namazi Hospital

Protocol summary

Study aim
Determining and comparing the amount of reaching the target calories 48 hours after the start of enteral nutrition between two groups during the study Determining and comparing the incidence of gastrointestinal intolerance between the two groups during the study. Determining and comparing the duration of hospitalization in ICU between two groups during the study

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, on 60 patients will be used for randomization using a block randomization table.

Settings and conduct
In both groups, patients will be fed with 1 kcal formula per cc. In the intervention group, gastric residual volume (GRV) will not be measured before feeding the patient, and the nurse will start feeding according to the protocol in the intensive care unit (ICU) and will proceed until the target calories , if symptoms of intolerance are observed , the patient's nutrition will continue according to the developed protocol, in the control group, GRV will be measured before feeding the patient and feeding is done based on the protocol. characteristics of patients and daily reports will be collected in a designed form.

Participants/Inclusion and exclusion criteria
Inclusion criteria -Age equal to or over 18 years old - Patients who have enteral nutrition through a nasogastric or orogastric tube after tracheal intubation and are expected to be mechanically ventilated for more than a week. Exclusion Criteria: - gastrointestinal surgery - Pregnancy - gastrostomy and jejunostomy

Intervention groups
In the intervention group: gastric residual volume will not be measured In the control group: gastric residual volume will be measured

Main outcome variables
The amount of reaching the target calories 48 hours after the start of enteral feeding

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20171217037916N3**
Registration date: **2023-10-08, 1402/07/16**
Registration timing: **prospective**

Last update: **2023-10-08, 1402/07/16**
Update count: **0**

Registration date
2023-10-08, 1402/07/16

Registrant information

Name
Zahra Mousavi Shirazi Fard

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2024-04-20, 1403/02/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determining the effect of not measuring the gastric residual volume on the success rate in achieving the target calorie of enteral nutrition in patients with endotracheal tubes hospitalized in the intensive care units of Namazi Hospital

Public title
The effect of gastric residual volume measurement on calorie intake in patients admitted to the intensive care unit
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age equal to or older than 18 years Patients who have enteral nutrition through a nasogastric or orogastric tube after tracheal intubation and are expected to be mechanically ventilated for more than a week
Exclusion criteria:
Patients who have had gastrointestinal surgery pregnancy Patients with gastrostomy and jugenostomy tubes
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization table will be used.After determining the sequence of random allocation, the names of the groups are placed in closed envelopes based on the agreed names of A and B respectively and based on the specified sequence. These envelopes are numbered in order. After the subjects entered the study and performed the initial assessments, a sealed envelope, based on the order placed, containing the contracted name of the participant's assigned group, which was determined based on the sequence of random assignment by a person outside the study, was opened for the individual to name Determine the contract of the assigned group. In this way, the allocation sequence is blinded for the executive team.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, in order to hide the random assignment, the names of the groups are placed in closed envelopes based on the conventional names A and B, respectively and based on the specified sequence. The participants in the study will not be aware of which group they have been assigned to until the end of the study, and the data analyst will not be aware of the assigned group and the intervention until the end of the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
6th Floor, Administration Building of Shiraz University of Medical Sciences Zand St., Shiraz, Iran
City
Shiraz
Province
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Postal code
7134814336
Approval date
2023-06-11, 1402/03/21
Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1402.075

Health conditions studied

1

Description of health condition studied
Patients undergoing mechanical ventilation in the intensive care unit
ICD-10 code
Z99.1
ICD-10 code description
Dependence on respirator

Primary outcomes

1

Description
The rate of reaching the target calories 48 hours after the start of enteral feeding
Timepoint
7 days
Method of measurement

The amount of feeding received by the patient during 24 hours will be collected by the nurse, then it will be divided by the amount of feeding ordered by the doctor, and then the percentage will be multiplied If the resulting number is equal to or more than 90% within 48 hours after the start of enteral feeding, it will be considered that the target calories have been reached.

Secondary outcomes

1

Description
Vomiting, diarrhea, abdominal distension, length of stay in ICU, mortality in ICU
Timepoint
7 days
Method of measurement
Designed form

Intervention groups

1

Description
Intervention group: Not to measure gastric residual volume before each feeding of the patient for 7 days
Category
Other

2

Description
Control group: measurement the gastric residual volume before each feeding of the patient according to the existing protocol for 7 days
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Nemazee hospital
Full name of responsible person
Zahra Mousavi Shirazi Fard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Zahra Mousavi Shirazi Fard
Position
Assisstant professor
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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
Not applicable