

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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hashem Hashempur

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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

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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