

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of two methods of feeding tubes through periodic and continuous flow methods, to achieve the caloric goal and its complications in patients hospitalized in ICU wards

Protocol summary

Summary

Comparison of two methods of feeding tubes through periodic and continuous flow methods, in terms of achieving the calorie goal and its complications in patients hospitalized in ICU wards. Nutritional support of patients under critical conditions and attention to the caloric requirements in order to reduce the fat, protein metabolism and malnutrition, is one of the aspects of caring patients under critical conditions. The frequency of gastrointestinal complications and cut off food in those patients is high. The purpose of this study is Comparison of two methods of feeding tubes through periodic and continuous flow methods, in terms of achieving the caloric goal, calorie intake and its complications in patients hospitalized in ICU wards. Design: After getting permission from the head Employee of Namazi Hospital this intervention study was carried out in intensive units. Methods: After getting the consent form, the form of a clinical trial was conducted on 60 patients hospitalized in the intensive care unit. Inclusion criteria: patients Over 18 years old; disable of getting food through mouth; feeding through a tube for at least 3 days ; using a standard formula. Exclusion criteria of study: active gastrointestinal bleeding; volunteers to receive a specific type of formula; use of gasterostomy tubes; known disorders in absorbing food and having a history of surgery to remove part of the digestive organs, Impossible to bring up the bed above 30 degree, such as spinal cord injuries. Patients were randomly classified into two groups by random numbers table, in case group, the patients were fed continuously and in control group, the patients were fed intermittently. Data on complications and time required to reach caloric goal and intake calorie, were collected in a checklist for a 7-day period. It was then analyzed with Chi-score and t-student tests. First Main outcome: Determine the time required to achieve the target calories, calorie intake and

incidence of cases of food intolerance.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109287655N1**

Registration date: **2011-10-09, 1390/07/17**

Registration timing: **na**

Last update:

Update count: **0**

Registration date

2011-10-09, 1390/07/17

Registrant information

Name

Somayeh Zahraei Fard

Name of organization / entity

Ahvaz university of medical science, nursing university

Country

Iran (Islamic Republic of)

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Recruitment status

Not enough for processing

Funding source

Vice chancellor for research, Shiraz and Ahvaz University of Medical Sciences

Expected recruitment start date

2011-11-16, 1390/08/25

Expected recruitment end date

empty

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
Comparison of two methods of feeding tubes through periodic and continuous flow methods, to achieve the caloric goal and its complications in patients hospitalized in ICU wards

Public title
Comparison of two methods of feeding tubes through periodic and continuous flow methods, to achieve the caloric goal and its complications in patients hospitalized in ICU wards

Purpose
Prevention

Inclusion/Exclusion criteria
inclusion criteria: Older than 18 years; the ability to receive food by mouth; fed through a tube at least 3 days ; using a standard formula. Exclusion criteria of study: active gastrointestinal bleeding; candidate receiving a specific type of formula; use of gasterestomy tubes ;known problems in absorbing food and having a history of surgery to remove part of the digestive organs.; Impossible to bring up the bed, such as spinal cord injuries

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Jondishapoor- Ahvaz university of medical science

ethics committee
Street address
Ahvaz university of medical science, Golestam street,
Ahvaz
City
Ahvaz
Postal code
Approval date
2011-05-21, 1390/02/31
Ethics committee reference number
ETH-176

Health conditions studied

1

Description of health condition studied
"nutrition status"

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Time to achieve caloric
Timepoint
During 7 days
Method of measurement
Per day inserted in check list

2

Description
Calories found
Timepoint
During 7 days
Method of measurement
K cal inserted in check list

3

Description
Food intolerance
Timepoint
During 7 days
Method of measurement
cc inserted in check list

Secondary outcomes

1

Description
Diarrhea and vomiting
Timepoint
During 7 days that study carried out
Method of measurement
yes or no

2

Description

During hospitalization

Timepoint

Till 6 month after intervention

Method of measurement

per day

3

Description

during ICU

Timepoint

Till 6 month after intervention

Method of measurement

per day

Intervention groups

1

Description

pump feeding

Category

Treatment - Other

2

Description

intermittent feeding

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Farid Zand

Street address

Namazee hospital, Zand street, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Hatam

Street address

Shiraz university of medical science, Zand street, Fars, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mostafa Fegghi

Street address

Ahvaz university of medical science, Golestan street, Ahvaz

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Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Ahvaz University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz university of medical science

Full name of responsible person

Sedighe Fayazi

Position

master of nursing

Other areas of specialty/work

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Anesthesiologist

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

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty