Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparing the effects of nasogastric feeding intervals on feeding tolerance in Intensive Care Unit patients

Protocol summary

Summary

The aim of the present study is implementing changes in the time interval in bolus method feeding, for proposing a proper diet to reduce the occurrence of intolerance in Intensive Care Unit hospitalized patients. The study population in this clinical trial is patients who are admitted in general intensive care unit of Hamedan Besat Hospital. 63 participants are selected from the patients and will be exposure the intervention. For participants are necessary to be 18 years old or more, have endotracheal tube and to be under bolus method NG-tube nutrition. Also participants are excluded in the case of death or transfer of the unit or to be made NPO due to the diagnostic and therapeutic procedures. Then the patients were randomly divided into three feeding groups with SPSS software. In the first group formula every 2 hours with 200 ml volume, in the second group formula every 3 hours with 300 ml volume and in the third group formula every 4 hours with 400 ml volume will be administrated. The formula and the feeding method is similar in all 3 groups. Before entering the study, Acute Physiology And Chronic Health Evaluation ‖ and Glasgow Coma Scale will be used to determine the severity of the condition and level of consciousness. In every groups (2, 3 or 4 hours), this feeding designated schedule will be done for three days. During these three days intolerance complications include regurgitation, diarrhea and gastric residual volume will be controlled and recorded by the trained nurse or the investigator, finally the intolerance complications will be compared in different intervals and appropriate diet will be recommended.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081718832N1**

Registration date: **2015-05-16, 1394/02/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-16, 1394/02/26

Registrant information

Name

Samaneh Sadeghi Hedayat

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 813839472

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of nasogastric feeding intervals on feeding tolerance in Intensive Care Unit patients

Public title

Effect of time interval on feeding tolerance in ICU

patients

Purpose

Supportive

Inclusion/Exclusion criteria

Patients are eligible for inclusion if they: are nasogastric tube fed via Bolus infusion; ≥18 years of age; are expected to have an ICU length of stay (LOS) >3days; don’t have diabetic disease, renal /hepatic failure because they need special formulas such as diabetic formula, hepatic formula; patients who are not immunocompromised; don’t have gastrointestinal diseases or surgery during recent 6 weeks; don’t have drug abuse history; don’t use drugs that increase gastrointestinal motility; don’t have diarrhea before the study. Participants are excluded from the study if they: need gastrointestinal motility enhancing drugs; change of feeding methods or formula during study; have gastric residual volume more than 200 ml; have gastrointestinal complications by another reasons; die or transfer from ICU to another wards; be made NPO due to the diagnostic and therapeutic procedures

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **63**

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

Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences, Shahid Fahmide Boulevard, Hamedan

City

Hamedan

Postal code

38698-65178

Approval date

2015-02-07, 1393/11/18

Ethics committee reference number

16/35/9/6169/پ

Health conditions studied

1

Description of health condition studied

diarrhoea

ICD-10 code

K59.1

ICD-10 code description

Functional diarrhoea

2

Description of health condition studied

regurgitation

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

3

Description of health condition studied

high gastric residual volume

ICD-10 code

R19.8

ICD-10 code description

Other specified symptoms and signs involving the digestive system and abdomen

Primary outcomes

1

Description

regurgitation

Timepoint

during 24 hours for 3 days

Method of measurement

inspection

2

Description

dification

Timepoint

during 24 hours for 3 days

Method of measurement

inspection

3

Description

gastric residul volume

Timepoint

every 4 hours during 3 days

Method of measurement

using 60 ml syring

Secondary outcomes

1

Description
pulse rate
Timepoint
every 3 hours
Method of measurement
monitoring system

2

Description
systolic blood pressure
Timepoint
every 3 hours
Method of measurement
monitoring system

3

Description
diastolic blood pressure
Timepoint
every 3 hours
Method of measurement
monitoring system

4

Description
body temprature
Timepoint
every 3 hours
Method of measurement
Mercurial thermometer

Intervention groups

1

Description
1st group: enteral nutrition via bolus infusion every 2 hours with 200 ml volume of standard formula for 3 days
Category
Prevention

2

Description
2nd group: enteral nutrition via Bolus infusion every 3 hours with 300 ml volume of Standard Formula for 3 days
Category
Prevention

3

Description
3rd group: enteral nutrition via Bolus infusion every 4 hours with 400 ml volume of Standard Formula for 3 days
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Hamedan Besat Hospital
Full name of responsible person
Samaneh Sadeghi Hedayat
Street address
Besat hospital, Shahid Motahary boulevard, Resalat square,Hamedan
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan university of medical science
Full name of responsible person
Dr. Saeed Bashirian
Street address
Hamedan university of medical science, Shahid Fahmide boulvard, Hamedan
City
Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan university of medical science
Proportion provided by this source
100
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
Hamedan university of Medical Science
Full name of responsible person
Samaneh Sadeghi Hedayat
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Bachelor of nursing/Student
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Person responsible for scientific inquiries

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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