

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)

Phone

+98 813839472

Email address

s.sadeghihedayat@umsha.ac.ir

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) > 3 days; 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 boulevard, 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

Position

Bachelor of nursing/Student

Other areas of specialty/work**Street address**

Hamedan University of Medical Science, Shahid
Fahmide boulevard, Hamedan

City

Hamedan

Postal code

Phone

+98 81 3038 0572

Fax

Email

s.sadeghihedayat@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Science

Full name of responsible person

Khodayar Oshvandi

Position

PhD in nursing

Other areas of specialty/work

Street address

Hamedan university of medical science, Shahid
Fahmide boulevard, Hamedan

City

Hamedan

Postal code

Phone

+98 81 3838 0150

Fax

+98 988138380447

Email

oshvandi@umsha.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Science

Full name of responsible person

Samaneh Sadeghi Hedayat

Position

Bachelor of nursing

Other areas of specialty/work

Street address

Hamedan University of Medical Science, Shahid
Fahmide boulevard, Hamedan

City

Hamedan

Postal code

Phone

+98 81 3839 4472

Fax

Email

s.sadeghihedayat@umsha.ac.ir

Web page address

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