

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of bolus and intermittent tube feeding impacts on intolerance nutrition and respiratory aspiration among sepsis patients in intensive care unit

Protocol summary

Summary

Objectives: This study is a clinical trial aiming to compare the tube feeding and bolus alternative methods on the level of nutrition intolerance and aspiration among hospitalized intensive care unit patients with sepsis.

Design: Random allocation **Setting and conduct:** Sixty patients with diagnosis of sepsis that were admitted to the intensive care unit of the Shahid Chamran hospital.

Major Inclusion criteria: Patients aged between 18 to 65 years old ; hospitalized in intensive care units ward ; and with confirmed diagnosis of sepsis ; level of consciousness lower 10 and with intubated.

Major Exclusion criteria : Any patient with increased or enough alertness and natural ability to eat while the study is conducted; discharged from the ICU before 10th day of hospitalization; hemodynamic disorders; need for new therapeutic interventions; history of dehydration symptoms; addiction.s

Interventions: First stage: Pre-test level in which patients to be assessed for study inclusion criteria. Second stage: patients randomly divided into three groups based on random allocation including: bolus, intermittent and continuous nutrition. Third stage: intervention study For these three noted methods for feeding, a Check list of steps will be prepared dependent upon related variables. Fourth stage: Three days after the beginning of the study, patients will classified into three groups according to the criteria of the nutrition intolerance and respiratory aspiration. main outcome measures: constipation; vomiting; residual volume; distension of gastric; Diarrhea

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015102623446N2**

Registration date: **2016-03-25, 1395/01/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-25, 1395/01/06

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Aja University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of bolus and intermittent tube

feeding impacts on intolerance nutrition and respiratory aspiration among sepsis patients in intensive care unit

Public title

Comparative study of bolus and intermittent tube feeding

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: aged between 18 to 65 years old; admitted to the intensive care units diagnosed with sepsis; the level of consciousness of less than 10; inability to eat through oral way and compelling need to nutritional support; lack of digestive disorders after confirming ICU physician; intubated the patient.

Exclusion criteria: increasing level of consciousness and develop the ability to eat during the study; discharge from ICU 10 days before admission; hemodynamic disorders and the need for new therapeutic intervention; signs of dehydration; addiction: receiving proton pump inhibitors; the need for a change in diet and the need to prescribe a specific diet during the study.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Units assigned to three groups nutrition bolus, intermittent and control The randomly by throwing dice, Thus, the number 1 and 2 of the first experimental group (bolus) The number 3 and 4 of the second test group (intermittent) and the number 5 and 6 of the control group

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

AJA University of Medical Sciences

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Approval date

2015-10-26, 1394/08/04

Ethics committee reference number

IR.AJAUMS.REC.1394.38

Health conditions studied

1

Description of health condition studied

sepsis

ICD-10 code

A40, A41

ICD-10 code description

Streptococcal sepsis, Other sepsis

Primary outcomes

1

Description

diarrhea

Timepoint

Three Days

Method of measurement

Check List

2

Description

constipation

Timepoint

Three Days

Method of measurement

Check List

3

Description

Puke

Timepoint

Three Days

Method of measurement

Check List

4

Description

Residual Volume

Timepoint

Three Days

Method of measurement

Check List

5

Description

Abdomen Stretch

Timepoint

Three Days

Method of measurement

Check List

Secondary outcomes

1

Description

Aspersion

Timepoint

Three

Method of measurement

Chck List

Intervention groups

1

Description

Intervention group 1:bolus feeding. The gavage will be performed gently using a syringe within 15-60 minutes depending on the condition and required volume.

Category

Other

2

Description

intervention group 2: intermittent. The intermittent nutrition using the pump for at least 4 and up to 20 hours depending on the conditions and required volume.

Category

Other

3

Description

control group: In the control group routine procedure in the ICU for fed carried out.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Martyr Chamran Hospital

Full name of responsible person

Mojtaba Ahangari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Aja University of Medical Sciences

Full name of responsible person

Dr. Kamran Azma

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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, Aja University of Medical Sciences

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

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Full name of responsible person

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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*