Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 diognosis 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 between18 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
Street address
AJA University of Medical Sciences, Etemadzadeh St, Fatemi St, Tehran
City
Tehran
Postal code
4813718414
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
Aspirsion
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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Tehran

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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AJA University of Medical Sciences, Etemadzadeh St., Fatemi St, Tehran
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Tehran
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
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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