

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effect of two methods of bolus and continuous enteral feeding on biochemical and clinical indicators of trauma patients admitted to intensive care units

Protocol summary

Study aim

Comparison of continuous and bolus nasogastric feeding on biochemical and clinical indicators of trauma patients admitted to ICU

Design

Randomised, superiority, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site

Settings and conduct

Researchers will refer to Shahid Beheshti Hospital after obtaining permission from the Vice Chancellor for Research and the Ethics Committee of the University of Medical Sciences. according to the patient's conditions who are not able to give written consent to participate in the study, his legal guardian will be obtained after stating the objectives of participation in the study. Preparing and performing the intervention: Intestinal feeding in the form of bolus for 10-20 ml using a 50 cc syringe. The amount of gavage solution in 24h, which is determined based on volume, calories and tolerance. In the continuous feeding group through a feeding pump, a special food bag every 4-6 h, 20-50 cc/h, which is determined based on volume, calories and tolerance

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- 18-60 years. 2- Being hospitalized in the ICU. 3- Intestinal nutrition through the nasogastric tube. 4- The patient isn't in critical condition. 5- trauma. 6- No renal or liver impairment; Exclusion criteria: 1- Nasogastric tube exit. 2- Intravenous feeding. 3- The patient's intestinal feeding be stopped for some reasons for > 24 h. 4- changes of gavage solution. 5- Death of the patient, surgery. 6- Reluctance to continue cooperation on behalf of the patient's guardian

Intervention groups

continuous feeding (Intervention)-bolus feeding (Control)

Main outcome variables

Biochemical : Alb, total pr, WBC, whole blood lymphocytes, Hb, htc, ur, cr, Ca, P, mg; Clinical: the number of bowel movements and remaining volume > 150 ml, aspiration, gastric bleeding, vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100124003146N10**

Registration date: **2022-07-19, 1401/04/28**

Registration timing: **prospective**

Last update: **2022-07-19, 1401/04/28**

Update count: **0**

Registration date

2022-07-19, 1401/04/28

Registrant information

Name

Ismail Azizi-Fini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

azizi-es@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two methods of bolus and continuous enteral feeding on biochemical and clinical indicators of trauma patients admitted to intensive care units

Public title

Comparison of two methods of bowel feeding and continuous in intensive care patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being hospitalized in the intensive care unit Intestinal feeding through the nasogastric tube is prescribed by a doctor Have stable and normal hemodynamic conditions. The patient has a head trauma.

Exclusion criteria:

Age over 60 years The patient has intravenous nutrition The patient has a kidney or liver disorder

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block randomization method was used in blocks 4 and 6, which were prepared using the online randomization software (www.sealedenvelope.com). In this software, two groups A (continuous feeding group) and B (bolus feeding group) were defined. Then, according to the total number of samples, which was 74, to increase the validity of randomization, two blocks of 6 and 4 blocks were defined with the approval of a statistician. Then, the researcher will be present in the section and will put the samples with the word criteria into groups based on the list obtained from the randomization software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, nurses will only be aware of the type of gavage for the patient, but will not know which patient is in the experimental group and which patient is in the control group. Also, the person who collects the study data and the person who will analyze them will not know

the names of the groups and only the names of the groups will be marked with the letters A and B.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of the Faculty of Nursing and Midwifery, Health and Paramedicine - Kashan Universit

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5th kilometer Qotb Ravandi blouvar

City

kashan

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Isfahan

Postal code

8715981151

Approval date

2022-05-16, 1401/02/26

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1401.023

Health conditions studied**1****Description of health condition studied**

Nutritional support in intensive care

ICD-10 code

E43

ICD-10 code description

Unspecified severe protein-calorie malnutrition

2**Description of health condition studied**

Nutritional support in intensive care

ICD-10 code

J98.4

ICD-10 code description

Other disorders of lung

Primary outcomes**1****Description**

Remaining volume in the stomach

Timepoint

Daily

Method of measurement

Gavage syringe(50 cc)

2**Description**

level of Albumin

Timepoint

Before intervention, 3 and 7 days after intervention

Method of measurement

Blood biochemistry test device

3**Description**

Number of intestinal excretions

Timepoint

daily

Method of measurement

checklist

4**Description**

Occurrence of pulmonary aspiration

Timepoint

daily

Method of measurement

checklist

5**Description**

Number of vomiting

Timepoint

daily

Method of measurement

checklist

6**Description**

Stomach bleeding

Timepoint

daily

Method of measurement

checklist

7**Description**

Total blood protein level

Timepoint

Before intervention, 3 and 7 days after intervention

Method of measurement

Blood biochemistry test device

8**Description**

White blood cell level

Timepoint

Before intervention, 3 and 7 days after intervention

Method of measurement

Blood analyzer

9**Description**

Whole blood lymphocyte count

Timepoint

Before intervention, 3 and 7 days after intervention

Method of measurement

Blood analyzer

10**Description**

Blood hemoglobin level

Timepoint

Before intervention, 3 and 7 days after intervention

Method of measurement

Blood analyzer

11**Description**

Hematocrit level

Timepoint

Before intervention, 3 and 7 days after intervention

Method of measurement

Blood analyzer

12**Description**

blood urea level

Timepoint

Before intervention, 3 and 7 days after intervention

Method of measurement

Blood biochemistry test device

13**Description**

Blood creatinine level

Timepoint

Before intervention, 3 and 7 days after intervention

Method of measurement

Blood biochemistry device

14**Description**

Blood calcium level

Timepoint

Before intervention, 3 and 7 days after intervention

Method of measurement

Blood biochemistry device

15**Description**

Blood phosphorus level

Timepoint

Before intervention, 3 and 7 days after intervention

Method of measurement

Blood biochemistry device

16

Description

Blood phosphorus level

Timepoint

Before intervention, 3 and 7 days after intervention

Method of measurement

Blood biochemistry device

17

Description

Blood cholesterol level

Timepoint

Before intervention, 3 and 7 days after intervention

Method of measurement

Blood biochemistry device

18

Description

Blood triglyceride levels

Timepoint

Before intervention, 3 and 7 days after intervention

Method of measurement

Blood biochemistry device

19

Description

Blood aspartate aminotransferase level

Timepoint

Before intervention, 3 and 7 days after intervention

Method of measurement

Blood biochemistry device

Secondary outcomes

1

Description

weaning from the ventilator

Timepoint

End of intervention

Method of measurement

Checklist

Intervention groups

1

Description

The enteral nutrition group will be the intervention group in a continuous manner. In the intervention group, enteral feeding will be done continuously (for 24 hours and in the form of an infusion of 20 drops per minute, which will be 2000 cc for a total of 24 hours). The food item (Karen's Standard Intermeal powder) will be prepared and given by the nutrition expert in a standard way for both groups in the same volume every 24 hours. The duration of intervention in both groups will last seven days.

Category

Treatment - Other

2

Description

The control group will be given enteral feeding in the form of bolus using a gavage syringe and under gravity every 3 hours, 250 cc of food will be given in 10 to 20 minutes, for a total of 24 hours of 2000 cc of standard Intrameal solution dissolved by a nutritionist. , will be given. The food item (Karen's Standard Intermeal powder) which will be prepared and given by the nutrition expert in a standard way for both groups in the same volume every 24 hours. The duration of intervention in both groups will last seven days.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital of kashan

Full name of responsible person

Ismail Azizi-Fini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Hamidreza Banafshe

Street address

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Azizi-es@kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Ismail Azizi-Fini

Position

assisstant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

the results related to the main outcome will be distributed

When the data will become available and for how long

after the publication of the article

To whom data/document is available

All people

Under which criteria data/document could be used

data will be confidential

From where data/document is obtainable

azizifinies@yahoo.com

What processes are involved for a request to access data/document

En the process will be announced later

Comments