# 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'nt 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 blues for 10-20 m 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- 8-60 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)

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+98 31 5554 0021

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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
**Street address**
5th kilometer Qotb Ravandi blouvar
**City**
kashan
**Province**
Isfehan
**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
**Street address**
5th kilometer Qotb Ravandi Blouvar.Parastar blouvar
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**Email**
azizifinies@yahoo.com
**Web page address**

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Kashan University of Medical Sciences
**Full name of responsible person**
Dr Hamidreza Banafshe
**Street address**
5th Kilometer Qotb Ravandi.Kashan university of medical sciences
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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

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

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**Position**

ãssisstant professor

**Latest degree**

Ph.D.

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## Person responsible for updating data

**Contact**

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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**