Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative clinical outcomes and nutritional status in hypocaloric vs. fullcaloric enteral tube feeding in trauma patients during the first week of hospitalization in intensive care unit

Protocol summary

Summary

Target of study: Comparative clinical outcomes and nutritional status in hypocaloric vs. full caloric enteral tube feeding in trauma patients during the first week of hospitalization in intensive care unit. Design: Randomized controlled trial, Single blinded, with controlled group, Single center. Target group: Traumatic patients admitted to Shahid Kamyab (Emdadi Hospital) intensive care unit. Inlusion criteria: All traumatic patients between 18-65 years admitted to ICU with diffuse axonal injury grade3&4 who do not need surgery, cannot eat sufficiently and are considered to stay a minimum of 96 hours in intensive care unit. Exclusion criteria: Patients less than 18 years old with a BMI ≤18.5 kg/m2who are expected to stay less than 96 hours and cannot receive enteral feeding within 48 hours of admission or have a Past medical history of terminal illness, diabetes, Liver or kidney dysfunctions, Immuno metabolic diseases, pancreatitis and a refused consent. Sample size: 60 patients. Intervention: All patients admitted to ICU are screened for eligibility. Once patient is eligible for study, informed consent is obtained from the next of kin. The patient is then randomized to one of the following arms: 1. Patients in the control group receive the Full-caloric diet. They receive a target of 90-100% of caloric requirement within 24-48 hours of admission via enteral nutrition support and continue to this method until the 7th day of intervention. 2. Patients in the intervention group receive the Hypo-caloric diet. The calorie intake of these patients is increased gradually and until they receive to the 100% of their calorie needs in the 7th day of intervention and after that they are fed same like the control group. Intervention duration: 7days. Primary outcomes: 28 day l mortality. Secondary outcomes: Hospital length of stay, severity of disease, Duration of mechanical ventilation Anthropometric and metabolic factors

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201128709N1**
Registration date: **2012-02-22, 1390/12/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-02-22, 1390/12/03

Registrant information

Name
Maryam Kazemi
Name of organization / entity
Mashad University of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 51 1882 8888
Email address
kazemim891@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashad University of Medical Science

Expected recruitment start date

2012-03-05, 1390/12/15

Expected recruitment end date

2012-05-04, 1391/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative clinical outcomes and nutritional status in hypocaloric vs. fullcaloric enteral tube feeding in trauma patients during the first week of hospitalization in intensive care unit

Public title
The effect of calorie intake on traumatic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Traumatic patients between 18-65 years old with diffuse axonal injury grade3 & 4 who do not need surgery, cannot eat sufficiently and are considered to stay a minimum of 96 hours in intensive care unit Exclusion criteria: Patients less than 18 years old, who are expected to stay less than 96 hours DNR (Do Not Resuscitate; no code, no escalation) in first 12 hours of admission. Enteral feeding cannot be started within 48 hours of admission. Admission BMI of less than 18.5 kg/m2 Past medical history of Terminal illness, diabetes, Liver or kidney dysfunctions, Immunometabolic diseases, pancreatitis Refused consent
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: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashad University of Medical Science
Street address
Faculty of Medicine, Azadi Square, Pardis Campus, Mashhad-Iran
City
Mashad
Postal code
91779-48564
Approval date
2011-11-08, 1390/08/17
Ethics committee reference number
900382

Health conditions studied

1

Description of health condition studied
Trauma
ICD-10 code
S06,S07,S0
ICD-10 code description
Intracranial injury,Crushing injury of head,Traumatic amputation of part of head,Other and unspecified injuries of head

Primary outcomes

1

Description
Mortality
Timepoint
28th day mortality
Method of measurement
Searching for the patient via HIS system or asking The patient's relatives

2

Description
Duration of hospital stay
Timepoint
Day 14 of intervention
Method of measurement
Days of hospital stay in the first 14 days of intervention

3

Description
Severity of disease
Timepoint
Day 0, 7 and 14 of intervention
Method of measurement
APACHE Score II

4

Description
Duration of mechanical ventilation
Timepoint
Day 14 of intervention
Method of measurement
Days of mechanical ventilation in the first 14 days of intervention

Secondary outcomes

1

Description
CRP Level
Timepoint
Day 0, 7 and 14 of intervention
Method of measurement
Laboratory Test

2

Description
Prealbumin Level
Timepoint
Day 0, 7 and 14 of intervention
Method of measurement
Laboratory Test

3

Description
Fasting Blood Sugar Level
Timepoint
Day 0, 7 and 14 of intervention
Method of measurement
Laboratory Test

4

Description
Electrolytes Level(Magnesium, Sodium, Phosphorous, Ptassium)
Timepoint
Day 0, 7 and 14 of intervention
Method of measurement
Laboratory Test

5

Description
Lipid Profile((LDL.C,TG,Total cholesterol, HDL.C)
Timepoint
Day 0, 7 and 14 of intervention
Method of measurement
Laboratory Test

6

Description
Liver Function Tests(ALT, AST, Total Billirubin)
Timepoint
Day 0, 7 and 14 of intervention
Method of measurement
Laboratory Test

7

Description
Total Lymphocytes Count
Timepoint
Day 0, 7 and 14 of intervention
Method of measurement
Laboratory Test

8

Description
Mid Arm Circumference
Timepoint
Day 0, 7 and 14 of intervention
Method of measurement
Measurement (cm)

9

Description
SGA Malnutrition Assessment
Timepoint
Day 0, 7 and 14 of intervention
Method of measurement
SGA Malnutrition Assessment Tool

Intervention groups

1

Description
Patients in the control group receive the Full-caloric diet. Once hemodynamically stable, they receive a target of 90-100% of caloric requirement (estimated by simple equation of rule of thumb that is 25 kcal/kg IBW) within 24-48 hours of ICU admission via enteral nutrition support and continue this method until the 7th day of intervention.
Category
Treatment - Other

2

Description
Patients in the intervention group receive the Hypo-caloric diet. After heamodynamically stabled, these patients are fed enterally with the permissive underfeeding method and they receive 40-50% of real calorie requirement (9-10 kcal/kg IBW) initially. The calorie intake of these patients is increased gradually and until they meet the 100% of their calorie needs in the 7th day of intervention and after that they are fed same like the control group.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Kamyab Hospital
Full name of responsible person
Maryam Kazemi
Street address
Shahid Kamyab Hospital, Fadaieyan Eslam Avenue,

Nakhrisi Square, Mashhad-Iran
City
Mashad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashad University of Medical Sceince
Full name of responsible person
Abdolreza Norouzy
Street address
Faculty of Medicine, Azadi Square, Pardis Campus, Mashhad-Iran
City
Mashad
Grant name
511/2815 (شماره نامه تصویب طرح)
Grant code / Reference number
900382
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashad University of Medical Sceince
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
Mashad University of Medical Science
Full name of responsible person
Maryam Kazemi
Position
Assistan professor/PhD Nutrition
Other areas of specialty/work
Street address
Faculty of Medicine, Azadi Square, Pardis Campus, Mashhad-Iran
City
Mashad
Postal code
91779-48564
Phone
+98 51 1882 8888
Fax
+98 912 288 0172
Email
Kazemim891@mums.ac.ir mar_kaz@yahoo.com
Web page address
www.mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashad University of Medical Science
Full name of responsible person
Abdolreza norouzy
Position
Assistan Professor/PhD Nutrition
Other areas of specialty/work
Street address
Faculty of Medicine, Azadi Square, Pardis Campus, Mashhad-Iran
City
Mashad
Postal code
91779-48564
Phone
+98 51 1800 2359
Fax
+98 51 1800 2421
Email
norouzy@gmail.com
Web page address
www.mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashad University of Medical Science
Full name of responsible person
Maryam Kazemi
Position
BS nutrition
Other areas of specialty/work
Street address
Faculty of Medicine, Azadi Square, Pardis Campus, Mashhad-Iran
City
Mashad
Postal code
91779-48564
Phone
+98 51 1882 8888
Fax
+98 51 1800 2421
Email
Kazemim891@mums.ac.ir mar_kaz@yahoo.com
Web page address
www.mums.ac.ir

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