

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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. Inclusion criteria: All traumatic patients between 18-65 years admitted to ICU with diffuse axonal injury grade 3&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/m² who 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 I 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

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Iran (Islamic Republic of)

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+98 51 1882 8888

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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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashad University of Medical Science

Full name of responsible person

Abdolreza Norouzy

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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 Science

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

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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