

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Efficacy of enteral nutrition with commercial formula and Taurine Supplementation on Clinical outcome and nutritional status of Critically ill burned patients in burned intensive care unit

Protocol summary

Summary

The aim of this study is to evaluate the effect of Taurine supplement and different enteral nutrition type (commercial or blenderized) on the inflammatory factors and clinical outcome of critically ill burned patients with systemic inflammatory response syndrome in intensive care unit. A single blinded, clinically randomized controlled trial is designed on 45 ICU patients aged between 18 - 85 years old. These patients are divided into three groups of 15, with enteral nutrition initiated in the first 6-24 hours of injury. Patients with TBSA of burn > 20% and enteral nutrition requirement of at least 48 hours, without renal or hepatic failure. First group is given enteral hospital nutrition (control group), the second group receives commercial standard formula nutrition, while the third group receives enteral commercial standard formula and 50mg/kg/bw taurine supplement. Energy requirement is calculated by Harris Benedict equation. Duration of intervention is 10 day. Primary outcome is assessed by SOFA score pattern change by measuring organ dysfunction evaluation. The secondary outcome is assessed by any alteration in immune system and nutritional status, measuring plasma taurine level, IL-10, TNF- alpha, hs-CRP and prealbumin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307082017N13**

Registration date: **2014-03-17, 1392/12/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-17, 1392/12/26

Registrant information

Name

Alireza Ostadrahimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Center of Infectious and Tropical Diseases

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of enteral nutrition with commercial formula and Taurine Supplementation on Clinical outcome and nutritional status of Critically ill burned patients in burned intensive care unit

Public title

Efficacy of enteral nutrition with commercial formula and Taurine Supplementation on Clinical outcome and nutritional status of Critically Ill burned patients in

burned intensive care unit

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Burned patients between the age 18 and 85 years with total body surface area of burn more 20%; enteral feeding requirement of at least 48 h and expected length of >48h stay in the ICU; patients without hepatic failure; renal failure; inborn errors of amino-acid metabolism; metabolic acidosis (pH less 7.35); absolute contraindication to enteral nutrition; non pregnant woman. Exclusion criteria: patients who died before the end of intervention; patients unable to tolerate enteral feeding.

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
Golgashat street, Tabriz University of Medical Sciences

City
Tabriz

Postal code

Approval date
2013-01-20, 1391/11/01

Ethics committee reference number
91187

Health conditions studied

1

Description of health condition studied

burn

ICD-10 code

T30-2, T30

ICD-10 code description

Burn of second degree, body region unspecified, Burn of third degree, body region unspecified

Primary outcomes

1

Description

Clinical outcome measurement

Timepoint

day 1,3,6,9

Method of measurement

Sequential Organ Failure Assessment (SOFA) score

Secondary outcomes

1

Description

Effect on Immune System

Timepoint

Baseline and end of intervention

Method of measurement

TNF-alpha (ELISA test), Interleukin 10 (IL-10) (ELISA test), High sensitivity C reactive protein (hs-CRP) (ELISA test)

2

Description

Effect on Nutritional Status

Timepoint

Baseline and end of intervention

Method of measurement

Prealbumin (Immunoturbidometric assay)

Intervention groups

1

Description

Hospital routine Nutrition (Control Group)

Category

N/A

2

Description

(Intervention Group1) energy requirement is calculated by harris benedict equation, enteral nutrition starts with 25ml/h enteral standard formula and increases to goal. Duration of intervention is ten days.

Category

Treatment - Other

3

Description

Intervention Group 2: energy requirement is calculated by harris benedict equation, enteral nutrition starts with 25ml/h standard enteral formula and increases to goal. 50 mg/kg BW.day of Taurine is given to patients. Duration of intervention is ten days.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Alireza Ostadrahimi

Street address

Azadi Street, Sina Hospital

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Center of Infectious and Tropical Diseases,
Tabriz University of Medical Sciences

Full name of responsible person

Dr Behrouz Naghili

Street address

Azadi Street, Sina Hospital

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Center of Infectious and Tropical Diseases,
Tabriz 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

Name of organization / entity

Faculty of Nutrition, Tabriz University of Medical Sciences

Full name of responsible person

Sima lak

Position

Ph.D Student of Nutrition

Other areas of specialty/work

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Golgasht Street, Attar Neyshaboori Avenue, Faculty of Nutrition, Tabriz University of Medical Sciences

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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