Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effects of Arginine and Citrulline supplementation on the prognosis of critically ill patinents in intensive care unit receiving enteral nutrition

Protocol summary

Summary

Our aim is to compare the effects of Arginine and Citrulline supplementation on the prognosis of critically ill patinents in intensive care unit receiving enteral nutrition,A total of 105 critically traumatic patients admitted to the intensive care units and receive entral nutritional support will be recruited and randomly allocated into three groups. patients are head trauma patients graid 2,3.Two groups will be intervened each by citrulline or arginine (10 gam/day for 10 days) and the third group will revived just enteral nutritional support without immune supplements. pateints are between 20 -70 years old, with BMI:18.5-30, and eligible of enteral nutrition support.Septic, Hemodynamically and metabolically unstable patients, and more than 3 days NPO will be excluded from the study.This clinical trial will be executed in 5 trauma ICUs at a trauma center in teaching hospital of Kamyab in Mashhad, Three groups will be compared for clinical severity (evaluaes with APACHI II score), length of hospital stay and complications, inflammatory state (CRP,IL6) nutritional markers (RBP, Pre-Albumine), lipide profile (LDL-C, HDL-C, Cholestrol, Triglycirid), plasma glucose, electrolytes, liver enzymes levels(AST, ALT, ALP, LDH total), NO production, PAB(Pro-oxidant and Anti oxidant Balance), urea and creatinine. Serum levels of Arginine, Citrulline, Ornithine, Glutamine and lysine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108027199N1**
Registration date: **2011-10-28, 1390/08/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-10-28, 1390/08/06

Registrant information

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Bahareh Barkhidarian
Name of organization / entity
Mashad univesity of medical science
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Mashad university of medical sciences and P.N.C food supplement company

Expected recruitment start date

2011-09-29, 1390/07/07

Expected recruitment end date

2011-12-28, 1390/10/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Arginine and Citrulline supplementation on the prognosis of critically ill patinents in intensive care unit receiving enteral nutrition

Public title

Comparison of Arginine and Citrulline

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: AGE:20-70 years old ;BMI:18.5-30
Exclusion criteria: hemodynamically and metabolically unstable patients; more than 3 days NPO; any condition that we can not use enteral feeding

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashad university of medical sciences

Street address

Sakhteman ghoreishi, Daneshgah street

City

Mashad

Postal code

91375345

Approval date

2011-01-15, 1389/10/25

Ethics committee reference number

89479

Health conditions studied

1

Description of health condition studied

head trauma patients

ICD-10 code

S06

ICD-10 code description

Intracranial injury

Primary outcomes

1

Description

death

Timepoint

28 days follow up

Method of measurement

daily assessment

2

Description

body mass index

Timepoint

day 0 and day 11 (first and last days of intervention)

Method of measurement

based on BMI equation

3

Description

ventilator depending

Timepoint

during hospital stay

Method of measurement

daily assessment

4

Description

lenght of hospital stay

Timepoint

in day of release

Method of measurement

based on date of admission and release

5

Description

ALT

Timepoint

day 0 and day 11 (first and last days of intervention)

Method of measurement

based on labratory measurement

6

Description

AST

Timepoint

day 0 and day 11 (first and last days of intervention)

Method of measurement

based on labratory measurement

7

Description

SEVIERITY OF ILLNESS

Timepoint

day 0 and day 11 (first and last days of intervention)
Method of measurement
APACHEII

8

Description
LDH
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

9

Description
ALP
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

10

Description
FBS
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

11

Description
BUN
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

12

Description
CREATININE
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

13

Description
CHOLESTROL
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

14

Description
LDL
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

15

Description
HDL
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

16

Description
TG
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

17

Description
BILLIRUBIN TOTAL
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

18

Description
DIRECT BILLIRUBINE
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

19

Description
Na
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

20

Description
potassium
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

21

Description
total calcium
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement

based on labratory measurement

22

Description
magnesium
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

23

Description
phpsphor
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

24

Description
albumine
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

25

Description
total protein
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

26

Description
nitric oxide
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

27

Description
pro oxidant _ anti oxidant balance
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

28

Description
pre albumine
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

29

Description
CRP
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

30

Description
IL6
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

31

Description
SERUM AMINO ACIDS(ARGININE, GLUTAMINE, CITRULLINE, LYSINE, ORNITHINE)
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

32

Description
weight
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

33

Description
Mid Arm Circumferences
Timepoint
day 0 and day 11 (first and last days of intervention)
Method of measurement
based on labratory measurement

Secondary outcomes

1

Description
side effect
Timepoint
during intervention
Method of measurement
daily assessment

Intervention groups

1

Description
Arginine group recieves 10 g/day arginine powder in 2

seprate 5 gram doses

Category

Treatment - Other

2

Description

Citrulline group recieves 10 g/day citrulline powder in 2 seprated 5 gram doses

Category

Other

3

Description

control group will not recieves any supplement

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

shahid kamyab hospital

Full name of responsible person

Street address

City

mashad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashad university of medical sciences

Full name of responsible person

Mashad university of medical sciences

Street address

Sakhteman Ghoreishi, Daneshgah street, Mashad

City

Mashad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashad university of medical sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Karen nutrilife co

Full name of responsible person

Ali Mazidi

Street address

number2, Atefi street, Afrigha blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karen nutrilife co

Proportion provided by this source

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 sciences

Full name of responsible person

Bahareh Barkhidarian

Position

MSC

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)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty