Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of the Effectiveness of High-protein Nutritional regimes with Normal regimes on Neuronal Bio-markers and Clinical Outcome of Neurocritical Patients

Protocol summary

Study aim

Determination of the effect of high protein diet (1.5 to 2 mg/kg/day) on serum level of Neuron specific Enolase (NSE) and Transthyretin, Nitrogen Balance and Glasgow Outcome Scale Extended in neurocritical patients

Design

Two arm parallel group randomized trial (control and intervention groups), not blinded and outcome assessment

Settings and conduct

Neurocretic patients admitted to the intensive care unit of Imam Hossein Hospital in Tehran are divided into two intervention and control groups and evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients older than 16 years old who have one of the following factors and stay in ICU for 5 days. (Subarachnoid Hemorrhage, Subdural Hematoma, Traumatic brain injury, Aneurysm, Intracranial hemorrhage, Others Exclusion criteria: Patient's death during the first three days of study Patient dis-admit with personal satisfaction within the first three days Disapprove of the patient to enter the research Contraindication of receiving high protein die Hepatic Encephalopathy An allergy to the drug Consumer of Warfarin Pregnancy Metabolic disorders (gout, phenylketonuria) Chronic renal failure Proteinuria is higher than 3 grams per day

Intervention groups

Intervention group: Receiving high protein diet (1.5 to 2 mg per kg daily) Control group: Receiving Regular diet of the intensive care unit

Main outcome variables

serum level of Neuron specific Enolase (NSE) serum level of Transthyretin Nitrogen Balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120703010178N14**
Registration date: **2018-04-11, 1397/01/22**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-11, 1397/01/22**
Update count: **0**

Registration date

2018-04-11, 1397/01/22

Registrant information

Name

Mohammad Sistanizad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 0087

Email address

sistanizadm@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2019-09-20, 1398/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effectiveness of High-protein Nutritional regimes with Normal regimes on Neuronal Bio-markers and Clinical Outcome of Neurocritical Patients

Public title
Effect of high protein regime in nurocritical patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients older than 16 years old who have one of the following factors and stay in ICU for 5 days. Subarachnoid Hemorrhage Subdural Hematoma Traumatic brain injury Aneurysm Intracranial hemorrhage Others

Exclusion criteria:
Patient's death during the first three days of study Patient dis-admit with personal satisfaction within the first three days Disapprove of the patient to enter the research Contraindication of receiving high protein die Hepatic encephalopathy An allergy to the drug Consumer of Warfarin Pregnancy Metabolic disorders (gout, phenylketonuria) Chronic renal failure Proteinuria is higher than 3 grams per day

Age
From **16 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of assigning each regimen to patients is randomized and random blocked blocks with block size 6 (using a permuted block randomization table).

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
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Velenjak Street, Shahid Chamran High Way

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2017-12-30, 1396/10/09

Ethics committee reference number
IR.SBMU.PHNM.1396.879

Health conditions studied

1

Description of health condition studied
Diseases of the nervous system injury

ICD-10 code
S06.2

ICD-10 code description
Diffuse traumatic brain injury

Primary outcomes

1

Description
Neuron Specific Enolase

Timepoint
At the beginning of the intervention (before the intervention) and 3 and 5 days after the beginning of the intervention

Method of measurement
Enolase CanAg kit

2

Description
Serum Transtreatin Level

Timepoint
At the beginning of the intervention (before the intervention) and 3 and 5 days after the beginning of the intervention

Method of measurement
Prealbumin Minineph *25T

3

Description
Nitrogen Balance

Timepoint
At the beginning of the intervention (before the intervention) and 5 days after the beginning of the intervention

Method of measurement
Based on urea concentration

Secondary outcomes

1

Description
Extended Glasgow Outcome Scale
Timepoint
The end of the first, second and third months after the begining intervention
Method of measurement
Score of Extended Glasgow Outcome Scale

2

Description
mortality
Timepoint
The end of the first, second and third months after the begining intervention
Method of measurement
Will be checked by phone

3

Description
Effect of medication on neuron specific Enolase
Timepoint
At the beginning of the intervention (before the intervention) and 3 and 5 days after the beginning of the intervention
Method of measurement
Blood sample

4

Description
Effect of medication on serum prealbumin level
Timepoint
At the beginning of the intervention (before the intervention) and 3 and 5 days after the beginning of the intervention
Method of measurement
blood sample

5

Description
Effect of medication on nitrogen balance
Timepoint
At the beginning of the intervention (before the intervention) and 5 days after the beginning of the intervention
Method of measurement
Urine sample

Intervention groups

1

Description
Intervention group: Prescribing protein (1.5-2 mg/kg/day) for 5 days
Category
Treatment - Other

2

Description
Control group: Prescribing a regular diet in the intensive care unit for 5 days
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Intensive care unit, Imam Hussein medical center
Full name of responsible person
Mohammad Sistanizad
Street address
Shahid Madani Street
City
Theran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8820 0087
Email
sistanizadm@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Tahereh Shams
Street address
Velenjak Street, Shahid Chamran High Way
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 23 87121
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Sistanizad
Position
Assistant Professor / Clinical Pharmacy Specialist
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Niayesh Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8820 0087
Email
sistanizadm@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Sistanizad
Position
Assistant Professor, Clinical Pharmacy Specialist
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Niayesh Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 218820087
Email
sistanizadm@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Forouzan Ahmadpour
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Niayesh Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
Ahmadpourforoz@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available