

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 neurocritical 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 Transtretatin 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 beginning 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 beginning 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

Tehran

Postal code

1985717443

Phone

+98 218820087

Email

sistanizadm@sbmu.ac.ir

Person responsible for updating data**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

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

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**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