

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparative study of Biceps Muscle Diameter under Ultrasound Guide in ICU & its Relation with Protein intake as a Indicator of Nutrition & Muscle atrophy

Protocol summary

Study aim

to compare protein delivery and muscle loss among patients who received a high protein enteral feeding and standard care.

Design

This was a randomized, double-blind, controlled clinical trial conducted at general ICU of Imam Hossein Hospital. A total of 100 patients were included. A random number generator software was used to prepare the randomization list.

Settings and conduct

Eligible patients were randomized in a 1:1 ratio to receive either the intervention or standard care. The intervention group received EN using a high-protein formula with a target protein delivery of 1.5 g/kg per day. The control group received standard nutrition care protocol, which aims to provide 1.0 g/kg/day protein. A blinded investigator (T.Sorbi) undertook the outcome measurements.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Adult aged 18-65 years admitted to ICU 2. Stay in ICU for at least 72 hours Exclusion criteria: 1. GCS less than 5 2. Unstable Arm fracture 3. Wound & infection of the arm 4. Upper extremity numbness 5. Upper extremity thrombosis 6. Musculoskeletal diseases 7. pregnancy 8. Liver disease 9. End-stage renal disease

Intervention groups

High-protein enteral nutrition group Standard care group

Main outcome variables

Changes in Biceps muscle thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200124046242N1**

Registration date: **2020-08-16, 1399/05/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-16, 1399/05/26**

Update count: **0**

Registration date

2020-08-16, 1399/05/26

Registrant information

Name

Tahereh Sorbi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2281 4083

Email address

t.sorbi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of Biceps Muscle Diameter under Ultrasound Guide in ICU & its Relation with Protein intake as a Indicator of Nutrition & Muscle atrophy

Public title

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult 18_65 years admitted to ICU Stay in ICU for at least 72 hours

Exclusion criteria:

GCS less than 5 Unstable Arm fracture Wound & infection of arm Upper extremity numbness Upper extremity thrombosis Musculoskeletal diseases pregnancy Liver disease End stage renal disease

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization with a block size of four was used for group allocation. The list of random numbers were generated using Excel software.

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

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

193954719

Approval date

2020-01-12, 1398/10/22

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

critical illness

ICD-10 code

M62.5

ICD-10 code description

Muscle wasting and atrophy, not elsewhere classified

Primary outcomes

1

Description

Biceps muscle thickness

Timepoint

Baseline and day 3, 6, 9, 12, 15, 18, 21

Method of measurement

muscle ultrasonography

2

Description

Nitrogen balance

Timepoint

Day 3 and day 5

Method of measurement

subtracting nitrogen losses from nitrogen intake according to the standard formula

Secondary outcomes

1

Description

Mortality

Timepoint

Day 21

Method of measurement

Death recorded in medical record

Intervention groups

1

Description

Intervention group: High-protein enteral nutrition

Category

Treatment - Drugs

2

Description

Control group: standard care

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Tahereh Sorbi

Street address

Madani Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 7755 8081

Fax

+98 21 7755 7069

Email

Intl_office@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Ziai

Street address

Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 2243 9770

Email

Intl_office@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

Tahereh Sorbi

Position

ICU Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Madani Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 7755 8081

Email

t.sorbi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Tahereh Sorbi

Position

ICU fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Madani Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 7755 8081

Email

t.sorbi@sbmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Tahereh Sorbi

Position

ICU Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Madani Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 7755 8081

Email

t.sorbi@sbmu.ac.ir

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The investigators refused to share individual data.

When the data will become available and for how long

The investigators refused to share individual data.

To whom data/document is available

The investigators refused to share individual data.

Under which criteria data/document could be used

The investigators refused to share individual data.

From where data/document is obtainable

The investigators refused to share individual data.

What processes are involved for a request to access data/document

The investigators refused to share individual data.

Comments