

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

Effect of parenteral human albumin on visceral proteins in critical patients

Protocol summary

Summary

The high prevalence of malnutrition and related problems in intensive care unit patients and controversial results in administration of intravenous albumin in these patients. This study is designed to determine the effect of intravenous albumin on the level of human visceral proteins in hospitalized patients in intensive care units, and the results of this study determined the efficiency of intravenous albumin to reduce malnutrition. This study is a randomized double-blind placebo-trials is done in the intensive care units. Inclusion criteria are adult patients with serum albumin less than 3.5 g/dl who endure the volume of gastric antral support at least 200 cc /3hr and have a minimum of 24 hours of ICU stay. Exclusion criteria are patients with enteral feeding intolerance up to 48 hours, patients with kidney and liver disease and any underlying medical condition that is associated with protein loss are excluded. After the final selection, participants were randomly divided into two groups; 1) intravenous human albumin supplement of 20 mg per day with a normal diet and 2) high protein diet + placebo. The period of the study is at least 6 days, and biochemical variables like serum albumin, pre-albumin, CRP levels were measured weekly throughout the project from beginning to end.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013073013160N3**
Registration date: **2013-11-03, 1392/08/12**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-11-03, 1392/08/12

Registrant information

Name

Shima Dehghan

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1624 5453

Email address

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Recruitment status

Recruitment complete

Funding source

Yazd Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2014-01-15, 1392/10/25

Expected recruitment end date

2014-07-16, 1393/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of parenteral human albumin on visceral proteins in critical patients

Public title

Effect of parenteral albumin on nutrition status in critical patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: adult patients; serum albumin less than 5/3 g per deciliter; have the power and volume of gastric antral support at least 200 cc every 3 hours; a minimum of 24 hours of ICU stay and not take part in another trial research. Exclusion criteria: patients with feeding intolerance antral; antral power outages up to 48 hours;

patients with kidney disease; liver disease and any underlying medical condition that is associated with protein loss are excluded. Patients who change the way they eat or be transferred to other centers throughout the city are also excluded.

Age

From **20 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoghi University of Medical Science

Street address

bahonar square- yazd

City

yazd

Postal code

8944157963

Approval date

2013-10-21, 1392/07/29

Ethics committee reference number

141748

Health conditions studied

1

Description of health condition studied

Protein-energy malnutrition

ICD-10 code

E43

ICD-10 code description

Unspecified severe protein-energy malnutrition

Primary outcomes

1

Description

prealbumin

Timepoint

weekly

Method of measurement

blood sample. mg/dl

2

Description

serum albumin

Timepoint

weekly

Method of measurement

blood sample. mg/dl

Secondary outcomes

empty

Intervention groups

1

Description

control group:high protein diet daily through Mifflin - Benedict is calculated and two vials of albumin placebo.

Category

Treatment - Drugs

2

Description

Intervention group: intravenous administration of human albumin 20% of physicians daily 2 vials Shhr Darou company received a normal diet under standard formula for calculating the Harris - Benedict are

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahnamoon hospital

Full name of responsible person

Dr. Ali Ghadami

Street address

shahid rahnamoon hospital-farokhi street-yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Science

Full name of responsible person

Dr. Mohammad Hossein Jarrahzade

Street address

bahonar square-yazd

City

Yazd

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yazd Shahid Sadoughi University of Medical Science

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**

Yazd Shahid Sadoughi University of Medical Science

Full name of responsible person

Shima Dehghan

Position

MSc student

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Web page address

Person responsible for updating data

Contact

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