

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Effect of alfa lipoic acid on biochemical and nutritional status and important outcomes in patients admitted to intensive care unit.

Protocol summary

Summary

Increasing Reactive oxygen and nitrogen production occurred simultaneously with decreasing serum and intracellular level of antioxidants and enzymes in critical ill patients, which result in increasing ventilator dependency and length of stay in intensive care unit and it also accelerate organ failures in patients. In this double blind clinical trial, we examine effect of alfa-lipoic acid on those patients who admitted to intensive care unit that we expect to stay for more than 7 days in this ward and who have tube feeding and don't have severe liver and kidney failure, AIDS and hepatitis. After randomization of included patients by block randomization we will give 900mg/day alfa-lipoic acid for ten days to treatment group and identical placebo to control group by naso-gastric tube. The purposes of this study are decreasing ventilator dependency period, length of stay in ICU, mortality and decelerate of organ failures.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302083236N4**

Registration date: **2013-06-06, 1392/03/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-06, 1392/03/16

Registrant information

Name

Zohreh Mazloom

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences (SUMS)

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of alfa lipoic acid on biochemical and nutritional status and important outcomes in patients admitted to intensive care unit.

Public title

Effect of alfa-lipoic acid on important outcomes in patients admitted to intensive care units

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age \geq 18; expected length of stay more than 7 days; using enteral feeding method during admitted to ICU. Exclusion criteria: having the history of autoimmune disease, severe renal or liver failure, AIDS, hepatitis; having severe malnutrition at the admission time; having TPN at the admission time in ICU; extreme intolerance to enteral feeding.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked*No information***Sample size**

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

shiraz university of medical sciences

Street address

iran, fars, shiraz,shiraz university of medical sciences

City

shiraz

Postal code**Approval date**

2013-01-26, 1391/11/07

Ethics committee reference number

91-6423

Health conditions studied**1****Description of health condition studied**

patients admitted in Intensive Care Unit

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

length of stay in ICU

Timepoint

at the end

Method of measurement

days

2**Description**

mortality

Timepoint

at the end

Method of measurement

number and percent

3**Description**

ventilator free days

Timepoint

during ICU stay

Method of measurement

daily assessment

Secondary outcomes**1****Description**

sequential organ failure assessment score

Timepoint

first and last days of intervention

Method of measurement

sequential organ failure assessment score questioniar

2**Description**

insulin resistance

Timepoint

first and last days of intervention

Method of measurement

HOMA calculation equation

3**Description**

malondialdehyde

Timepoint

first and last days of intervention

Method of measurement

spectrophotometry

4**Description**

total antioxidant capacity

Timepoint

first and last days of intervention

Method of measurement

ELIZA

5**Description**

C reactive protein

Timepoint

first and last days of intervention

Method of measurement

nephelometry

6

Description

interleukin-6

Timepoint

first and last days of intervention

Method of measurement

ELIZA

7

Description

Albumin

Timepoint

first and last days of intervention

Method of measurement

ELIZA

8

Description

preAlbumin

Timepoint

first and last days of intervention

Method of measurement

Turbidimetry

9

Description

Total lymphocyte count

Timepoint

first and last days of intervention

Method of measurement

microscopic count

10

Description

Mid arm circumference

Timepoint

first and last days of intervention

Method of measurement

centimeter

11

Description

total protein

Timepoint

first and last days of intervention

Method of measurement

based on laboratory measurement

Intervention groups

1

Description

alfa-lipoic acid 900mg/day for 10 days

Category

Treatment - Drugs

2

Description

placebo for 10 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital- emergency ICU

Full name of responsible person

Street address

City

Shiraz

2

Recruitment center

Name of recruitment center

Namazi hospital- general ICU

Full name of responsible person

Street address

Namazi hospital

City

Shiraz

3

Recruitment center

Name of recruitment center

Namazi hospital- central ICU

Full name of responsible person

Street address

Namazi hospital

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

shiraz university of medical sciences-vice chancellor
for research affairs

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

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**

shiraz university of medical sciences- nutrition department

Full name of responsible person

najmeh hejazi

Position

PhD candidate of Nutrition

Other areas of specialty/work**Street address**

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Web page address**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