

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effects of regular dose and elevated dose of trace element supplementation on nutritional status and general condition of burned injured patients admitted to BICU

Protocol summary

Study aim

Comparison of the effects of regular dose and elevated dose of trace element supplementation on nutritional status and general condition of burned injured patients admitted to Burn ICU

Design

Randomized clinical trial with control group, Parallel groups, single blinded, sample size is 48

Settings and conduct

This study will be performed in Taleghani hospital in Ahvaz in a single-blinded manner. 48 patients will be divided into two groups of intervention and control by block randomization method. The intervention group will be injected with two doses of Addamel each time; and the control group will be injected with one.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years Staying in ICU for more than 72 hours Burn percentage: between 20 and 60 Exclusion criteria: Patients with liver disorders Patients with Nephrotic Syndrome Hemodynamic instability Increased lactate in serum Pregnancy

Intervention groups

Control group: on the first ,third and fifth day of hospitalization patients will receive one dose of Addamel in the form of injection supplement. Intervention group: on the first ,third and fifth day of hospitalization patients will receive two doses of Addamel in the form of injection supplement.

Main outcome variables

hospitalization days ventilation time hospital-acquired infection rate changes in patients' nutritional status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200115046141N1**

Registration date: **2020-03-10, 1398/12/20**

Registration timing: **prospective**

Last update: **2020-03-10, 1398/12/20**

Update count: **0**

Registration date

2020-03-10, 1398/12/20

Registrant information

Name

Pegah Sajadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3337 1272

Email address

sajadi.p@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2021-01-04, 1399/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of regular dose and elevated dose of trace element supplementation on nutritional status and general condition of burned injured patients

admitted to BICU

Public title

trace element supplementation in burned patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Staying in ICU for more than 72 hours

Burn percentage: between 20 and 60

Exclusion criteria:

Patients with liver disorders Patients with Nephrotic Syndrome Hemodynamic instability Increased lactate in serum Pregnancy

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization with computer software

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants (patients) will not be informed that they are in the control or intervention group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Jundishapur university of Medical Sciences

Street address

No .19. East 23 street. Kian abad

City

Ahvaz

Province

Khuzestan

Postal code

6155764566

Approval date

2020-02-24, 1398/12/05

Ethics committee reference number

IR.AJUMS.REC.1398.909

Health conditions studied

1

Description of health condition studied

burn

ICD-10 code

T30-2, T30

ICD-10 code description

Burn of second degree, body region unspecified, Burn of third degree, body region unspecified

Primary outcomes

1

Description

hospitalization days

Timepoint

at the end of the study

Method of measurement

based on the number of the days

2

Description

ventilation time

Timepoint

at the end of the study

Method of measurement

based on the number of the days

3

Description

hospital-acquired infection rate

Timepoint

first , third and fifth day of hospitalization

Method of measurement

white blood cell count

4

Description

changes in patients' nutritional status

Timepoint

first , third and fifth day of hospitalization

Method of measurement

measuring blood indexes like albumin , creatinine, sodium and potassium

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: on the first ,third and fifth day of hospitalization patients will receive two doses of Addamel in the form of injection supplement.(three times and each time two doses) each dose contains:1.1 milligrams Iron,6.5 milligrams Zinc , 1.3 milligrams Copper, 0.27 milligrams Manganese, 0.13 milligrams Iodine , 32 micrograms Selenium , 10 micrograms Chromium , 19 micrograms Molybdenum, and 0.95 milligrams Fluorine

Category

Prevention

2

Description

Control group: on the first ,third and fifth day of hospitalization patients will receive one dose of Addamel in the form of injection supplement.(three times and each time one dose) each dose contains:1.1 milligrams Iron,6.5 milligrams Zinc , 1.3 milligrams Copper, 0.27 milligrams Manganese, 0.13 milligrams Iodine , 32 micrograms Selenium , 10 micrograms Chromium , 19 micrograms Molybdenum, and 0.95 milligrams Fluorine

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital for burn patients

Full name of responsible person

Peyman Nejati

Street address

across from number 23 police station, phase 2 of Padadshahr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Ahvaz Jundishapur University of Medical Science,
Golestan highway

City

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Province

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itc@ajums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Pegah Sajadi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Durdana Husain

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the financial support of this research project by Ahvaz Jundishapur University of Medical Science ,the study data will not be allowed to be published after the intervention.

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

Undecided - It is not yet known if there will be 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