

# 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

#### City

Ahvaz

#### Province

Khuzestan

#### Postal code

6187954386

#### Phone

+98 61 3554 0255

#### Email

p.nejati97@gmail.com

## 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

Ahvaz

#### Province

Khuzestan

#### Postal code

6135715794

#### Phone

+98 61 3336 2414

#### Fax

+98 61 3336 1544

#### Email

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

#### Street address

No. 19, East 23 Ave, Kian Abad

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sajadi.p@ajums.ac.ir

## 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**

Nutrition

**Street address**

Nutrition Department, Ahvaz Jundishapur University of Medical Science, Golestan highway

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**Email**

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## Person responsible for updating data

### 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

**Street address**

No. 19, East 23 Ave, Kian Abad

**City**

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**Province**

Khouzestan

**Postal code**

6155764566

**Phone**

+98 61 3337 1272

**Fax****Email**

sajadi.p@ajums.ac.ir

## 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