Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effect of Trehalose on survival and severity of disease in patients admitted to the intensive care unit

Protocol summary

Study aim
Evaluation of the effect of Trehalose on survival and severity of disease in patients admitted to intensive care unit

Design
Triple-blind parallel randomized clinical trial with control group, phase 2 on 200 patients. We will use the website (www.sealedenvelope.com) for randomization.

Settings and conduct
ICU admitted patients in Imam Reza hospital in Mashhad, with mentioned inclusion criteria, will be enrolled to this study after informed consent. They will be divided into two groups of intervention (Trehalose) and control (Normal saline). Before inclusion and in the fifth day of the study (or before discharge in case of discharging before the 5th day), blood sample will be taken to assess Blood Sugar (BS), Creatinine, liver enzymes, C-Reactive Protein and Complete Blood Count (CBC). Blood pressure, Glascow Coma Scale (GCS), APACHE, SOFA, Richmond Agitation Sedation Scale (RASS), along with mortality in ICU and 60-days mortality will be assessed and compared between two groups.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients admitted to ICU within the last 48 hours, over 18 years old, APACHE-II score > 15 (using values recorded from 24 hours before inclusion up to the time of inclusion), sign informed consent by the patients or his legal guardians. Exclusion Criteria: referral ICU patients from other centers after 1 week admission in other ICUs, pregnancy and breastfeeding

Intervention groups
Intervention group: IV infusion of Trehalose (15 mg with infusion speed of 4 mlit/min) made by Dr. Rajabi Pharmaceutical Co. Control group: Normal Saline 0.9% infusion with the same volume of the intervention group.

Main outcome variables
mortality in ICU, 60-days mortality, Blood Sugar, Creatinine, liver enzymes, C-Reactive protein, and CBC. Blood pressure, Glascow Coma scale (GCS), APACHE, SOFA, Richmond Agitation Sedation Scale (RASS).

General information

Reason for update
The minimum sample size was calculated as 182. Considering 10% drop out, we will try to enter 200 participants.

Acronym

IRCT registration information
IRCT registration number: **IRCT20130829014521N22**
Registration date: **2023-04-26, 1402/02/06**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-05, 1402/09/14**
Update count: **2**

Registration date
2023-04-26, 1402/02/06

Registrant information

Name
Amirhossein Sahebkar

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 51 1882 9260

Email address
sahebkara@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2025-04-21, 1404/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Trehalose on survival and severity of disease in patients admitted to the intensive care unit

Public title

The effect of Trehalose on survival of ICU admitted patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients admitted to the ICU within 48 hours prior to inclusion APACHE-II score > 15 (using values recorded from 24 hours before inclusion up to the time of inclusion) Over 18 years old Sign informed consent by the patients or his legal guardians

Exclusion criteria:

Referral ICU patients from other centers after 1 week admission in other ICUs. Pregnancy and breastfeeding

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization was done using the block sizes of 4 and 6 with randomization website (www.sealedenvelope.com). After randomization, the type of treatment is written A/B codes in separate papers. Using sequential numbering, a third party (who does not contact with patients) will numbered the vials with specific numbers related to the randomized codes (A,B).

Blinding (investigator's opinion)

Triple blinded

Blinding description

As mentioned before, after randomization, the patients place in two groups of A/B and received the products similar in shape and color (blinding of participants). The physician/nurse who will give the vials to the participants, received the vials with randomized codes and is not aware of the grouping (so the physician is blind too). The information of the patients and theirs vial numbers will be written on datasheets (the blinding of the assessor). Data will be entered to the SPSS software with codes (the blinding of the analyzer).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Mashhad University of Medical Sciences

Street address

Ghoreshi Building, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2023-04-08, 1402/01/19

Ethics committee reference number

IR.MUMS.REC.1402.026

Health conditions studied

1

Description of health condition studied

ICU admitted patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mortality in ICU

Timepoint

During hospitalization in the ICU.

Method of measurement

The mortality will be recorded in datasheets. No need to more measures.

2

Description

60-days mortality

Timepoint

Mortality during the 60 days after entering to the study

Method of measurement

In case of hospitalization, the 60-days mortality will be

assessed by using HIS (health information system) and the information in the hospital files. If the patient has been discharged from the hospital, the information will be obtained by phone call.

Secondary outcomes

1

Description
BS (Blood Sugar)
Timepoint
The blood sample will be taken before inclusion and in the fifth day of the study (In case of discharging before the 5th day, the blood sample will be taken before discharge).
Method of measurement
Blood test

2

Description
Creatinine
Timepoint
The blood sample will be taken before inclusion and in the fifth day of the study (In case of discharging before the 5th day, the blood sample will be taken before discharge).
Method of measurement
Blood test

3

Description
Liver enzymes including glutamic-oxaloacetic transaminase (SGOT) and Serum glutamic pyruvic transaminase (SGPT)
Timepoint
The blood sample will be taken before inclusion and in the fifth day of the study (In case of discharging before the 5th day, the blood sample will be taken before discharge).
Method of measurement
Blood test

4

Description
Complete Blood Count (CBC)
Timepoint
The blood sample will be taken before inclusion and in the fifth day of the study (In case of discharging before the 5th day, the blood sample will be taken before discharge).
Method of measurement
Blood test

5

Description
CRP (C-reactive protein)
Timepoint
The blood sample will be taken before inclusion and in the fifth day of the study (In case of discharging before the 5th day, the blood sample will be taken before discharge).
Method of measurement
Blood test

6

Description
Blood pressure
Timepoint
The blood pressure will be recorded before inclusion and in the fifth day of the study (In case of discharging before the 5th day, the blood pressure will be taken before discharge).
Method of measurement
Sphygmomanometer

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Description
GCS (Glascow coma scale)
Timepoint
The GCS will be recorded before inclusion and in the fifth day of the study (In case of discharging before the 5th day, the GCS will be taken before discharge).
Method of measurement
Add together the scores from eye opening, verbal response and motor response.

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Description
APACHE (Acute Physiology and Chronic Health Evaluation)
Timepoint
The APACHE will be recorded before inclusion and in the fifth day of the study (In case of discharging before the 5th day, the APACHE will be taken before discharge).
Method of measurement
According to scoring system (APACHE is a severity-of-disease classification system that estimates mortality based on a number of laboratory values and patient signs taking both acute and chronic disease into account. This score will be calculated based on the guidelines and recorded in the checklist).

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Description
SOFA (Sequential Organ Failure Assessment)
Timepoint
The SOFA will be recorded before inclusion and in the fifth day of the study (In case of discharging before the 5th day, the SOFA will be taken before discharge).
Method of measurement
According to scoring system (SOFA score is a scoring system that assesses the performance of several organ systems in the body).

10

Description

Richmond Agitation Sedation Score (RASS)

Timepoint

The RASS will be recorded before inclusion and in the fifth day of the study (In case of discharging before the 5th day, the RASS will be taken before discharge).

Method of measurement

According to scoring system (RASS is an instrument designed to assess the level of alertness and agitated behavior in critically-ill patients).

Intervention groups

1

Description

Intervention group: IV infusion of trehalose (15 mg, intravenous speed of 4mlit/min) made by Dr. Rajabi Pharmaceutical Co.

Category

Treatment - Drugs

2

Description

Control group: Normal Saline 0.9% infusion with the same volume of intervention group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Amirhossein Sahebkar

Street address

School of Pharmacy, University Campus, Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Phone

+98 51 3180 1000

Email

sahebkara@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour-Mobarhan

Street address

Ghoreshi Building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

Email

vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Amihossein Sahebkar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutical biotechnology

Street address

School of Pharmacy, University Campus, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Phone

+98 51 3180 1100

Email

sahebkara@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Amirhossein Sahebkar

Position
Associate professor

Latest degree
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Other areas of specialty/work
Pharmaceutical biotechnology

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City
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Province
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Postal code
9177948954

Phone
+98 51 3180 1100

Email
sahebkara@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Amirhossein Sahebkar

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
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School of Pharmacy, University Campus, Azadi square

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948954

Phone
+98 51 3180 1100

Email
sahebkara@mums.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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available