Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

A comparison of the effect of receiving albumin in the initial 8 to 12 hours and after 24 hours after burn on the incidence of fluid creep in severe burn patients

Protocol summary

Study aim
comparing the effect of receiving albumin in the first 8-12 hours or after 24 hours after burning on the incidence of fluid creep in severe burn patients

Design
The study is a randomized triple-blinded controlled clinical trial with a parallel design. This study will use block randomization. A sample size of 96 participants will be classified according to burn percent and the existence of inhalation injury, and in each group, patients will be randomized into either intervention or control group according to 2 or 4 randomized blocks.

Settings and conduct
The study will be done in velayat burn hospital, Rasht. The triple-blind study design will be used, blinding patients, outcome assessment team, and data analyst.

Participants/Inclusion and exclusion criteria
severe burn patients patients not needing albumin infusion according to the clinical decision of specialists, critically ill patients, patients with underlying conditions affecting serum albumin level or study outcomes, and patients with a history of response to human albumin will be excluded from the study.

Intervention groups
The intervention group will receive 20% human albumin 0.125 milliliters per kilogram body weight per percent body surface burn between 8 to 12 hours after admission as a 1-hour infusion. The control group will receive the same amount of albumin after 24 hours post-admission.

Main outcome variables
patient's fluid intake to maintain satisfactory urine output experiencing fluid creep

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210227050510N1**
Registration date: **2021-07-13, 1400/04/22**
Registration timing: **prospective**

Last update: **2021-07-13, 1400/04/22**
Update count: **0**

Registration date
2021-07-13, 1400/04/22

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2023-05-22, 1402/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparison of the effect of receiving albumin in the initial 8 to 12 hours and after 24 hours after burn on the

incidence of fluid creep in severe burn patients

Public title
An evaluation of the effect of albumin administration time on the incidence of fluid creep in severe burn patients

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
burn patients with 2nd and 3rd degree burn area more than 20 percent TBSA full-thickness burn area more than 10 percent TBSA patients needing vasopressor usage in the first 24 hours of admission patients needing intubation and mechanical ventilation in the first 24 hours of admission

Exclusion criteria:
patients not needing albumin infusion according to the clinical decision of specialist critically ill patients with expected death in first 24 hours or patients that expired in first 24 hours of admission brain death in first 24 hours patients admitted more than 8 hours after burn patients with chronic underlying diseases affecting serum albumin level, including nephrotic syndrome, cirrhosis, malnutrition, exudative enteropathy pregnancy a history of cardiac surgery or myocardial infarction in recent 5 years patients with high-voltage electrical burn injuries patient does not accept entering the study patients receiving plasmaphresis a history of reaction to human albumin

Age
From **1 year** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
In the presenting study, we employ categorized randomization. We classify the minimum sample size according to the existence of inhalation injury and burn surface area. To randomize the patients into intervention and control groups, we use restricted randomization with block randomization. We use randomized 2 or 4 member blocks to prevent revealing the last allocation in each block. Patients entering the study after completion of each block will enter new 2 or 4 member blocks. We classify patients according to burn surface area into 5 groups with 20-25, 25-30, 30-35, 35-40, and more than 40 percent total body surface area burn, and regarding inhalation injury into 2 groups having or not having inhalation injury.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Albumin will be infused into the patient's resuscitation fluids and the patient is not going to be aware of the time of albumin infusion. Data collection is done by observing team members that are not aware of the patient's allocation to either intervention or control groups, using the designed checklist. Data analysis is performed by the specialist that is not aware of A and B coding (and that which one is the intervention group).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committees of Guilan university of medical sciences

Street address
Deputy of Research and Technology of Guilan University of Medical Sciences, Siyadati St., Namjou Blvd., Rasht

City
Rasht

Province
Guilan

Postal code
3369741938

Approval date
2021-06-02, 1400/03/12

Ethics committee reference number
IR.GUMS.REC.1400.085

Health conditions studied

1

Description of health condition studied
Burn

ICD-10 code
T31

ICD-10 code description
Burns classified according to extent of body surface involved

Primary outcomes

1

Description
fluid creep, patient's fluid intake exceeding estimated intake with parkland formula

Timepoint

12 hours and 1,2,3,5, and 7 days after-burn

Method of measurement

assessment of the fluid intake of patient to maintain a satisfactory urine output

Secondary outcomes

1

Description

Length of hospital stay

Timepoint

At the time of hospital discharge

Method of measurement

Days

Intervention groups

1

Description

Intervention group: The intervention group will receive 20% human albumin 0.125 milliliters per kilogram body weight per percent body surface burn between 8 to 12 hours after admission as a 1-hour infusion.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive 20% human albumin 0.125 milliliters per kilogram body weight per percent body surface burn after 24 hours post-admission as a 1-hour infusion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

MohammadReza Mobayen

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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Mohammadreza Mobayen

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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