

# 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

##### Name

Amirhossein Tamimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3372 0988

##### Email address

apam997@gmail.com

#### 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 plasmapheresis 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

###### Street address

Velayat Hospital, Namjou St., Rasht

###### City

Rasht

###### Province

Guilan

###### Postal code

4193713191

###### Phone

+98 13 3336 8860

###### Fax

+98 13 3336 8651

###### Email

velayathospital@gmail.com

###### Web page address

<https://www.gums.ac.ir/velayat/default.aspx?tabid=431>

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Rasht University of Medical Sciences

###### Full name of responsible person

Mohammadreza Naghipour

###### Street address

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

###### City

Rasht

###### Province

Guilan

###### Postal code

6694941446

###### Phone

+98 13 3336 2889

###### Fax

+98 13 3336 2842

###### Email

research@gums.ac.ir

###### Web page address

<http://research.gums.ac.ir>

##### 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

General Surgery

**Street address**

Velayat Hospital, Namjou St., Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

4193713191

**Phone**

+98 13 3336 9633

**Email**

mmobayen@gums.ac.ir

**Person responsible for scientific 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**

General Surgery

**Street address**

Velayat Hospital, Namjou St., Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

4193713191

**Phone**

+98 13 3336 9633

**Email**

mmobayen@gums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Amirhossein Tamimi

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Velayat Hospital, Namjou St., Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

4193713191

**Phone**

+98 13 3336 9633

**Fax****Email**

amirhosseintamimi997@gmail.com

**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