

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

A clinical trial on comparing morbidity and mortality of restrictive blood transfusion strategy with a traditional strategy in patients with a thermal burn

Protocol summary

Study aim

Comparison of morbidity and mortality of restricted blood transfusion with liberal blood transfusion in thermal burn patients and evaluation of factors affecting blood transfusion rate

Design

a randomized clinical trial with two parallel control and intervention groups, with double-blinded evaluation of morbidity and mortality

Settings and conduct

During the study period, patients who referred to Shahid Motahari Burn Center with more than 20% of body surface burn, who were eligible for the study and had informed consent will participate in the study. After randomly dividing into control and intervention groups, they are treated according to liberal and restricted blood transfusion strategy, respectively. Information on admission, information on the length of stay, information on the amount of transfusions, and information on the consequences of hospitalization are recorded and analyzed.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: - Age over 18 years. - Having a serum hemoglobin level below 10 mg/dl. - The surface of burn above 20% - admission within the first 96 hours of burn
Exclusion Criteria: - History of Cardiovascular disorders - History of blood transfusion complications - pregnant or lactating - hematologic disorder

Intervention groups

Intervention group: Blood transfusion when the patient's blood hemoglobin is below 8 mg/dl
Control group: Blood transfusion when the patient's blood hemoglobin is below 10 mg/dl

Main outcome variables

Total number of transfused blood bags, mortality during hospitalization, inpatient morbidity (including wound infection, positive blood culture, sepsis, cardiac,

pulmonary, neurologic, and compartment syndrome), total episodes of infection (each infection), duration
Hospitalization time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190209042660N1**

Registration date: **2020-06-15, 1399/03/26**

Registration timing: **retrospective**

Last update: **2020-06-15, 1399/03/26**

Update count: **0**

Registration date

2020-06-15, 1399/03/26

Registrant information

Name

Hamid Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 0031

Email address

salehi.ha@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-22, 1397/06/31

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

2018-09-22, 1397/06/31

Actual recruitment end date

2019-09-22, 1398/06/31

Trial completion date

2019-09-22, 1398/06/31

Scientific title

A clinical trial on comparing morbidity and mortality of restrictive blood transfusion strategy with a traditional strategy in patients with a thermal burn

Public title

comparing morbidity and mortality of Restrictive blood transfusion with a traditional approach in patients with a thermal burn

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years Total Body Surface Area more than 20 percent Admission to the burn center where the study took place in first 96 hours after the injury

Exclusion criteria:

a known history of allergic reactions secondary to blood transfusions pregnancy history of requiring hemodialysis Brain death Angina or acute myocardial infarction known history of hematologic disorder blood transfusion at another center prior to admission those who were unlikely to survive, according to the experienced burn specialists impaired coagulation

AgeFrom **18 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **40**Actual sample size reached: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

Using the simple randomization method, all eligible patients were assigned to the intervention and control groups one by one before each procedure.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, each individual was randomly assigned to one of two intervention and control groups, with only one physician authoring the admission order for blood transfusion and the executing nurse being aware of the group to which the individual belongs. Each person is assigned a numeric code and the data is entered into the software by the lead researcher who has no knowledge of the strategy being executed against each code. The analyzer is aware of the strategy

implemented for each individual and reports the statistical results of the two groups analysis.

Placebo

Not used

Assignment

Other

Other design features

Following the meeting of the Research Council, the commencement of this research was reviewed by the Ethics Committee of Iran University of Medical Sciences and its implementation was morally permissible based on similar studies. Those who were included in the study were without any restriction on exclusion. The scholars of this project adhere to all Helsinki ethics. The routine burn management was done for all patients similarly. The hemoglobin level was frequently checked for early detection of any decline. Every patient who showed any sign of anemia received packed cell regardless of their order for threshold of transmission. After a blood transfusion, the patient's clinical symptoms and possible side effects will be assessed. All patients were given blood transfusions as much as required, during surgical procedures if they were hemodynamically unstable or had lost a large volume of blood, regardless of their protocol. After discharge, the researchers extracted and recorded all the data and information needed from the patient's file and hospital management system. Four categories of information were recorded for each patient as follows:

- At the time of admission: Demographic information including sex and age, smoking habits, depth and percentage of burns based on TBSA, co-incidence of inhalation burns, other factors that may affect blood transfusions, including heart disease, performing escharotomy on arrival.
- During admission: number and type of surgical procedure (including debridement, graft, early excision, escharotomy, amputation, surgery for associated trauma, etc.), length of stay in ICU, and coagulation disorder
- Information about blood transfusion: Hemoglobin levels before the first blood transfusion, total number of blood units received, number of units received per injection time (before the first surgery, during surgery and out of the operating room after surgery), length of hospital stays until the first injection
- Events occurred during the admission: Mortality during hospitalization for any cause, occurrence of complications (including wound infection, positive blood culture, sepsis, cardiac or pulmonary problems, neurologic defects and compartment syndrome), total number of episodes of infection (any kind of infection), duration of hospitalization, blood culture.

Secondary Ids

empty

Ethics committees1**Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical

Sciences

Street address

Iran University of Medical Sciences, next to Milad tower, Hemmat highway

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2019-02-10, 1397/11/21

Ethics committee reference number

IR.IUMS.FMD.REC.1398.009

Health conditions studied

1

Description of health condition studied

anemia

ICD-10 code

D62

ICD-10 code description

Acute posthemorrhagic anemia

2

Description of health condition studied

thermal burn

ICD-10 code

T31

ICD-10 code description

Burns classified according to extent of body surface involved

3

Description of health condition studied

blood transfusion side effects

ICD-10 code

Y64.0

ICD-10 code description

Contaminated medical or biological substance, transfused or infused

Primary outcomes

1

Description

Total unit of transfused blood

Timepoint

Discharge date

Method of measurement

Patient file

2

Description

total number of reported infection

Timepoint

Discharge date

Method of measurement

patient file

3

Description

Hospitalization time

Timepoint

discharge date

Method of measurement

patient file

4

Description

mortality rate during admission

Timepoint

discharge date

Method of measurement

patient file

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: blood transfusion when hemoglobin level is below 8 g/dl

Category

N/A

2

Description

Control group: blood transfusion when hemoglobin level is below 10 g/dl

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mottahari Burn Center

Full name of responsible person

Maziar Daniali

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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

Iran 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
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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Result of data analysis

When the data will become available and for how long

Start of access period from 2020

To whom data/document is available

General practitioners and specialists

Under which criteria data/document could be used

If they are studying similar field or consulting on a treatment decision

From where data/document is obtainable

Email Mr. Maziar Daniali to mazidani87@gmail.com

What processes are involved for a request to access data/document

Within 2 weeks of receiving the email request for data access

Comments