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)

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+98 21 8877 0031

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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
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target 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 committees

1

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
۱۴۴۹۶۱۴۵۳۵
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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Maziar daniali
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Resident of General Surgery
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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