Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of allogeneic transfusion after injection of injectable iron in patients' candidates for intertrochanteric fracture surgery

Protocol summary

Study aim
The amount of allogeneic transfusion after administration of injectable iron in patients candidates for fracture surgery

Design
A randomized clinical trial with a parallel standard treatment control group, phase 3, on 78 patients, randomization by computer random numbers.

Settings and conduct
The study in Shohada hospital is performed by double-blind method (researcher and patients) based on the fact that both of them are unaware of the group allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 65 years. Exclusion criteria: iron deficiency disorders, other anemia disorders, sensitivity to oral or injectable iron medications, asthma treatment with clopidogrel or acetylsalicylic acid, blood coagulation disorders, liver disease, hypothyroidism or hyperthyroidism, chronic kidney failure.

Intervention groups
The two groups will be under the treatment based on the protocol of the intertrocantric fracture treatment center of Shohada Tajrish hospital, Trauma Center. Patients in the case group will receive Venofer, manufactured by the French company Wafer, 10 days before surgery at a dose of 600 mg during a slow infusion, and no intervention will be performed for patients in the control group.

Main outcome variables
Bleeding during surgery; the rate of erythrocyte injection during surgery, hemoglobin and hematocrit, reticulocyte, and ferritin levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190121042444N4**
Registration date: **2021-10-20, 1400/07/28**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-20, 1400/07/28**
Update count: **0**

Registration date
2021-10-20, 1400/07/28

Registrant information

Name
faranak behnaz

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2274 1174

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faranak.behnaz@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-22, 1400/06/31

Expected recruitment end date
2023-09-22, 1402/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of allogeneic transfusion after injection of injectable iron in patients' candidates for intertrochanteric fracture surgery

Public title
The effect of injectable iron on blood transfusion rate in patients with hip fractures

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Intertrochanteric fractures Age over 65 years
Exclusion criteria:
Excessive iron disorders Other anemic disorders due to diseases such as thalassemia Chronic Diseases Megaloblastic anemia Sensitivity to oral or injectable iron Treatment of asthma with clopidogrel or with salicylic acetyl Blood coagulation disorders Liver diseases Hypothyroidism or hyperthyroidism Chronic renal failure
Age
From **65 years** old to **90 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants in the study are divided into two categories of control and intervention using Android randomization software IZE, so that first each patient raises a number and it is entered in the software and the output of the software shows a A and B groups. 78 patients will participate in this study and 39 of them will be allocated to intervention and the other 39 will enter control group based on randomization application.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients are introduced to the data collector to continue the study so that only the numbers A and B are written on the form in the patient's hand, and as a result, the patient and the data collector are not aware of the patient group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Behesti University of Medical Sciences
Street address
Yaman Ave,Velenjak
City
Tehran
Province
Tehran
Postal code
1467664961
Approval date
2021-08-09, 1400/05/18
Ethics committee reference number
IR.SBMU.MSP.REC.1400.244

Health conditions studied

1

Description of health condition studied
Femoral fractures
ICD-10 code
S72.1
ICD-10 code description
Intertrochanteric fracture

Primary outcomes

1

Description
Bleeding volume
Timepoint
Before the intervention and during surgery
Method of measurement
Based on measurements of the surgical field and the volume of suction

2

Description
Number of PRBC received
Timepoint
Before the intervention and during surgery
Method of measurement
Number of blood bags injected

3

Description
hemoglobin
Timepoint
Before intervention and 1 hour after surgery and 7 days after surgery
Method of measurement
Measurement of serum levels in a blood test

4

Description
Hematocrit
Timepoint
Before intervention and 1 hour after surgery and 7 days after surgery
Method of measurement

Measurement of serum levels in a blood test

5

Description
Ferritin
Timepoint
Before intervention and 1 hour after surgery and 7 days after surgery
Method of measurement
Measurement of serum levels in a blood test

6

Description
Reticulocytes
Timepoint
Before intervention and 1 hour after surgery and 7 days after surgery
Method of measurement
Measurement of serum levels in a blood test

7

Description
Red blood cell count
Timepoint
Before intervention and 1 hour after surgery and 7 days after surgery
Method of measurement
Measure the number in the blood test

8

Description
Iron level
Timepoint
Before intervention and 1 hour after surgery and 7 days after surgery
Method of measurement
Measurement of serum levels in a blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The group will be monitored by a specific orthopedic professor under the treatment protocol of intertrochantric fracture treatment center of Shohada Tajrish Hospital Trauma Center. And hemoglobin less than 8 or less than 9 grams per deciliter (in patients with a history of cardiorespiratory disease). Patients received a slow infusion of Venofer made by the French company Wifor at a dose of 600 mg (each ampoule of Venofer in 250 cc of diluted 9% saline solution will be infused once a day for 90 minutes from 10 days before surgery).
Category
Treatment - Drugs

2

Description
Control group: No intervention will be performed in this group. Standard treatment will be administrated.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Tajrish Hospital
Full name of responsible person
Faranak Behnaz
Street address
Shohada Hospital,Tajrish SQ ,Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Faranak Behnaz
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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
Only part of the data, such as information about the main consequence or the like, can be shared.
When the data will become available and for how long
Start of access period from 1401
To whom data/document is available
Only for researchers in academic and scientific institutions
Under which criteria data/document could be used
Only data analysis is possible
From where data/document is obtainable
Dr. Faranak Behnaz, Address: Tehran, Tajrish Square, Shohada Experience Hospital, Tel: 0098212271174
What processes are involved for a request to access

data/document

After submitting the application, a maximum of one week will be answered

Comments