

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

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

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

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

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

Update count: **0**

Registration date

2021-10-20, 1400/07/28

Design

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

Registrant information

Name

faranak behnaz

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2274 1174

Email address

faranak.behnaz@gmail.com

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.

Recruitment status

Recruitment complete

Funding source

Intervention groups

The two groups will be under the treatment based on the protocol of the intertrochanteric 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.

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

Main outcome variables

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

Scientific title

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190121042444N4**

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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nahid Asadi

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nahidasadi@yahoo.com

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 scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rahmatollah Mohammadzadeh

Position

Rezident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data**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

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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