Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the relationship between intravenous iron injection before spinesurgery in patients and improving perioperative outcomes, a randomized clinical trila.

Protocol summary

Study aim

intravenous iron injection before spine surgery in patients and improving the outcome around the action

Design

Clinical trial with a control group with parallel double-blind groups, phase 3 on 60 patients. K-S test was used to check the distribution of quantitative data. Chi-square test used to study the relationship between qualitative variables.

Settings and conduct

After going through legal procedures to access patient information and with the commitment not to disclose secrets Patients, permission to access the patients' files was obtained. This research is in the form of a work study A double-blind randomized clinical trial was conducted on patients who were candidates for spine surgeryTajrish Hospital performed. Patients classified into three groups (A), (B) and (C).Group (A) patients, have hemoglobin less than 13mg/dl in men and hemoglobin less than 12mg/dl in women and iron injection before surgery they received. Group (B) patients, had hemoglobin in the normal range They received an injection before the operation.group c have not recieved IV Iron. Injectable iron is used in the form of 500 mg in 1000 cc of normal saline, which is injected within 15 minutes to 1 hour. The iron is VENOFER type.

Participants/Inclusion and exclusion criteria

Exclusion criteria: patients who were allergic to iron, patients under 18 years old and over 70 years old. active infection, known hemosiderosis, known thalassemia major and intermedia, known nutrition in the acute phase of nutritional recovery, ferritin more than 300 ng/ml, and those categories Patients who did not consent. Inclusion criteria: patients undergoing posterior lumbar fusion surgery in at least 3 levels

Intervention groups

patients undergoing posterior lumbar fusion surgery in at least 3 levels

Main outcome variables

Infection, hospitalization, hemoglobin drop,The degree of welding of the beads

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230815059152N1**
Registration date: **2023-09-11, 1402/06/20**
Registration timing: **retrospective**

Last update: **2023-09-11, 1402/06/20**
Update count: **0**

Registration date

2023-09-11, 1402/06/20

Registrant information

Name

Farzan Fahim

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2680 0765

Email address

farzn.fahim@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-24, 1402/03/03

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

2023-05-26, 1402/03/05

Actual recruitment end date

2023-07-23, 1402/05/01

Trial completion date

empty

Scientific title

Investigating the relationship between intravenous iron injection before spinesurgery in patients and improving perioperative outcomes, a randomized clinical trila.

Public title

Investigating the effect of intravenous iron injection in spine surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range from 18 to 70years Patients undergoing posterior vertebral fusion surgery at least 3 levels

Exclusion criteria:

History of iron sensitivity Under 18 years and over 70 years known Cirrhosis of the liver known Thalassemia major Ferritin more than 300 ng/dl known Thalassemia Intermedia known Hemosiderosis known Active phase of nutritional deficiency

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The aforementioned study is a double-blind clinical trial, as follows: 1) The statistical analyst is outside the treatment team, and it is not clear to them whether group A, B or C has been subjected to intervention and the information of each of the three groups without being told in which of the groups the intervention took place. has been accepted and will be available to them. 2) The neurosurgery assistant present during the operation, (who is present as a clinical supervisor)so that all three groups of patients will undergo posterior instrumentation surgery, as well as the same surgical technique and the possibility of deviation by the surgeon during the operation, they are informed that this The patients are in the study, but they are not told which of the patients have undergone intravenous iron injection and intervention.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Volenjek St., in front of the fire station, corner of 16th St., Nirvana Building, No. 1

City

Tehran

Province

Tehran

Postal code

1985743855

Approval date

2023-08-27, 1402/06/05

Ethics committee reference number

IR.SBMU.MSP.REC.1402.219

Health conditions studied

1

Description of health condition studied

After posterior fusion surgery of lumbar vertebrae

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Duration of hospitalization after surgery

Timepoint

The beginning of the study and the end of the study

Method of measurement

Counting down the days

2

Description

Incidence of infection

Timepoint

Day 0 until the end of hospitalization

Method of measurement

Qualitative

3

Description
The degree of fusion of the vertebrae with an interval of one month after the operation
Timepoint
one month after the operation
Method of measurement
lenke scale

4

Description
Hemoglobin drop after surgery
Timepoint
Immediately after surgery, 14 days and then 28 days after surgery
Method of measurement
laboratory

Secondary outcomes

empty

Intervention groups

1

Description
The patients in the mentioned clinical trial study are in three groups (A), (B) and (C). All the patients who entered the Madaleh have signed a written consent form to perform the intervention and have received full explanations. Group (a) are those patients who have anemia in laboratory results before surgery, i.e. hemoglobin less than 13 gm/dL for men and less than 12 mg/dL for women. and they are supposed to undergo the intervention of intravenous iron injection. Group (b) are those patients who do not have anemia in laboratory tests before surgery and are supposed to undergo the intervention of intravenous iron injection,Group (c) is the control group that does not undergo the intervention of intravenous iron injection.Venofer intravenous iron comes in the form of vials containing 500 mg of iron, which is injected into the patient in 1000 cc of normal saline over a period of 15 minutes to 1 hour. Intravenous iron injection is done 24 hours before surgery in these patients. Before the injection, the patients' hemoglobin and ferritin levels are checked and recorded in laboratory tests. After surgery, laboratory tests are repeated at intervals of 1 day, 14 days, and then 28 days, and their levels are also recorded. Also, during hospitalization, patients are checked for the occurrence of infection at the operation site and also the duration of hospitalization. On the 28th day, the patients undergo a routine follow-up CT scan or a simple photo of the abdomen, and with the help of the Lenke criteria, we can classify the degree of swelling of the patients.All information and data are presented to a statistical expert for analysis. It should be noted that the statistical analyst is outside the treatment team and is blinded to the intervention. Also, neurosurgery assistants who are present during the surgery to prevent bias. The precision and technique during the operation is blind to the intervention.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
shohada-e-tajrish hospital
Full name of responsible person
saeed oraee yazdani
Street address
Tehran, Tajrish, Qods Square, Shahradari St., Shahada Tajrish Hospital
City
Tehran
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Tehran
Postal code
1989934148
Phone
+98 21 25719
Email
Pr_shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
afshin zarghi
Street address
بزرگراه تهران- شهید چمران - خیابان یمن - خیابان اعرابی- نرسیده به بیمارستان آیت الله طالقانی- دانشگاه علوم پزشکی و خدمات بهداشتی درمانی شهید بهشتی ساختمان شماره دو ستاد دانشگاه- طبقه ششم
City
Tehran
Province
Tehran
Postal code
4631- 19395.
Phone
+98 21 2243 9788
Email
urm@sbmu.ac.ir
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

farzan fahim

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Nirvana Building, No. 1, corner of 16th St., in front of the fire station, Volenjak St.

City

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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

farzan fahim

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

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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

farzan fahim

Position

medical student

Latest degree

A Level or less

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Phone

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Email

farzn.fahim@gmail.com

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

Duration of hospitalization from before operation to after Number of operated tubes Is there an infection at the surgical site or not? What was the initial and final hemoglobin level? Has it dropped or not? Are the changes meaningful?

When the data will become available and for how long

From 1403

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Natural and legal persons with university faculty status

From where data/document is obtainable

Farzan Fahim, mobile number 09120943182, email address farzn.fahim@gmail.com

What processes are involved for a request to access

data/document

First, send an email with your complete introduction, then the answer will be sent within 24 hours.

Comments