Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Role of preoperative intravenous iron in perioperative blood management after rhinoplastic surgery: A Clinical Trial

Protocol summary

Summary

Objectives: We aimed to use preoperative intravenous iron therapy in patients undergoing elective rhinoplastic surgery to improve preoperative hemoglobin concentrations, reduce the need for RBC transfusion, and decrease complications compared with placebo.Design: A randomized, double-blinded clinical trial is designed to evaluate the effects of preoperative intravenous iron in candidates for rhinoplastic surgery in Shiraz Rajaei Hospital. Sixty adult between the ages of 18-40 will be randomized to receive either intravenous iron or the placebo before rhinoplastic surgery.Setting and conduct: A questionnaire that included demographic information, medical history, hemodynamic values before, during and after the operation, duration of surgery, and the amount of intraoperative bleeding will be recorded. Bleeding collected with surgical gauzes and the amount of blood in the suction device will be calculated as the total amount of intraoperative bleeding. Inclusion criteria: Adult patients; no history of drug use; willingness to cooperate in the study. Exclusion criteria: known allergy to the study drug; history of thromboembolic episodes; iron overload; hematologic diseases; hepatic and renal dysfunction; preoperative autologous blood donation and lack of signed informed consent. Intervention: The intervention group will receive an intravenous VENOFER-iron sucrose injection, 500 mg dissolved in normal saline 0.9 % via pump infusion for 30 min. Patients in the control group will receive " placebo" as same bolus volume in a 30-minute intravenous infusion. Main outcome measures: Hemodynamic values, intraoperative estimated blood loss (EBL) and surgical duration.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701221674N14**

Registration date: **2017-06-02, 1396/03/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-02, 1396/03/12

Registrant information

Name

Hamid Reza Eftekharian

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2017-05-15, 1396/02/25

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Role of preoperative intravenous iron in perioperative blood management after rhinoplastic surgery: A Clinical Trial

Public title
Efficacy of preoperative intravenous iron in perioperative blood management after rhinoplastic surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Male or female patients more than 18 years of age; no history of drug use; and willingness to cooperate in this study are enrolled. Exclusion criteria: patients with known allergy to the study drug; history of thromboembolic episodes; iron overload; hematologic diseases; hepatic and renal dysfunction; preoperative autologous blood donation and lack of signed informed consent will be excluded.
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee Of Shiraz University Of Medical Sciences
Street address
Shiraz University of Medical Sciences, Vice-Chancellors of Research and Technology, Zand Avenue, Shiraz
City
Shiraz
Postal code
1978-71345
Approval date
2017-02-06, 1395/11/18
Ethics committee reference number
IR.SUMS.REC.1395.29

Health conditions studied

1

Description of health condition studied
Bleeding during rhinoplasty
ICD-10 code
00
ICD-10 code description
00

Primary outcomes

1

Description
Hemoglobin concentration
Timepoint
Pre operatio and post operation
Method of measurement
Questionnaire Lab. (g/dL)

Secondary outcomes

1

Description
Transfused blood products
Timepoint
perioperatively
Method of measurement
number of units

2

Description
Hemoglobin
Timepoint
Post operative
Method of measurement
g/dL

3

Description
Blood Pressure
Timepoint
During administration
Method of measurement
Blood pressure monitoring

Intervention groups

1

Description
Intervention group: Patients in the interventional group (first group) will be received an intravenous VENOFER-iron sucrose injection, 500 mg dissolved in Norma salin 0.9 % via pump infusion bolus for 30 min. 25mg of Venofer should be infused over a period of 15 minutes. If no adverse events occur during the test dose, the

remainder of the dose should be given at an infusion rate of not more than 50ml in 15 minutes.

Category

Treatment - Drugs

2

Description

Control group: Patients in the the second group will received " placebo" as same bolus volume dissolved in Norma salin 0.9 % in a 30-minute intravenous infusion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Rajaei Hospital

Full name of responsible person

Farhad Ghorbabi

Street address

Shiraz University Of Medical Sciences, Shiraz Rajaei Hospital, Chamran Blvd., Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Basir Hashemi

Street address

Shiraz University of Medical Sciences, Vice-Chancellery of Research and Technology, Zand Avenue, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz School of Dentistry

Full name of responsible person

Saeed Tavanafar

Position

Resident of Maxillofacial Surgery

Other areas of specialty/work

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Position

Associate Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty