Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effect of Tidal Volume on operative blood loss in patients undergoing posterior spinal fusion in Firozgar hospital during 2012-2013

Protocol summary

Summary

Spinal fusion surgery is often associated with a high rate of bleeding. The aim of this study is examining the effect of patients ventilation with two different amount of tidal volume(low & usual volume) on the amount of blood loss during posterior spinal fusion (PSF) surgery. So in a randomized double blind clinical trial, 34 patients 18-60 years old with ASA class I and II, candidated for PSF, will be divided in two group. Anesthesia plan and drugs are the same in both group. In group (1) after prone positioning, patients will be ventilated with 6 ml/kg tidal volume but in group (2) 10 ml/kg TV will be used. other setting are the same between two group. The volume of blood loss during the operation (blood collected in suction reservoir and bloody sponges) calculated as the initial outcome. and surgeon satisfaction from the operative field will be assessed by a standard scoring system as the secondary outcome. Collected data will be analysed and compared between two group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100111398N4**
Registration date: **2013-11-12, 1392/08/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-11-12, 1392/08/21

Registrant information

Name

Mohammad Reza Ghodraty

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 6762

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, vice Chancellor for research affairs

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Tidal Volume on operative blood loss in patients undergoing posterior spinal fusion in Firozgar hospital during 2012-2013

Public title

Evaluation of the effect of tidal Volume on operative blood loss

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients who candidate for posterior spinal fusion under general anesthesia; Consent to participate in research project; ASA physical status I-II; Age between 18 years old to 60 years old; BMI< 30

Exclusion criteria: Disagreement for participation; ASA physical status more than II; Emergency surgery; History of previous spinal surgery; Respiratory diseases; Coagulopathies; Cardiovascular disease; Hypertension; Kidney or liver disease; Diabetes Mellitus; History of taking drugs such as: beta blockers; Calcium channel blockers; Digoxin; Anticoagulant; Clonidine; Alcohol and drug abuse; Tumor in the site of surgery

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Deputy of Iran University of Medical Sciences, Ethics Committee

Street address
5th Floor, central building, Iran University of Medical Sciences, Hemmat Highway

City
Tehran

Postal code
-

Approval date
2012-06-25, 1391/04/05

Ethics committee reference number
1037- 05.04.91

Health conditions studied

1

Description of health condition studied
Thoracho-lumbar spine fracture

ICD-10 code
T02.1

ICD-10 code description
Fractures involving thorax with lower back and pelvis

Primary outcomes

1

Description
The volume of blood loss during surgery

Timepoint
End of surgery

Method of measurement
Volume of blood collected in the suction reservoir and bloody sponges.

Secondary outcomes

1

Description
Surgeon satisfaction from operative field

Timepoint
End of operation

Method of measurement
Standard scoring score

Intervention groups

1

Description
In intervention group after giving the prone position to the patients, ventilation with low tidal volume (6 ml/kg) will be used until the end of surgery.

Category
Other

2

Description
In control group traditional value of tidal volume (10 ml/kg) will be used for ventilation during operative period

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Firoozgar Hospital

Full name of responsible person
Mohammad Reza Ghodraty MD.

Street address
Department of Anesthesia, Firoozgar Hospital, Beh-Afarin St. Karim Khan Av.

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research deputy, Iran University of Medical Siences
Full name of responsible person
Dr Motavalian MD.
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5th floor, central bulding, Iran University of Medical Sciences, Hemmat Highway
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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
Research deputy, Iran University of Medical Siences
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
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Person responsible for updating data

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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