

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 Ghodrati

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 6762

Email address

m-ghodrati@tums.ac.ir

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

Thoraco-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 Ghodratty 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 Sciences

Full name of responsible person

Dr Motavalian MD.

Street address

5th floor, central bulding, Iran University of Medical Sciences, Hemmat Highway

City

Tehran

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 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

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Ghodrati MD.

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work**Street address**

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

City

Tehran

Postal code**Phone**

+98 21 8894 6762

Fax**Email**

m-ghodrati@tums.ac.ir mrgodrati@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammadreza Ghodrati, Dr

Position

Assistant proffesor of Anesthesia

Other areas of specialty/work**Street address**

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

City

Tehran

Postal code**Phone**

+98 21 8894 6762

Fax**Email**

m-ghodrati@tums.ac.ir mrgodrati@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Ghodrati MD.

Position

Assistant professor of Anesthesiology

Other areas of specialty/work**Street address**

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

City

Tehran

Postal code**Phone**

00

Fax**Email****Web page address**

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