

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of two ventilation methods "volume control & pressure control" on blood loss of posterior Spinal fixation surgery

Protocol summary

Summary

Aims: The key purpose of this study is to determine the impact of two approaches "volumetric and pressure ventilation" on intra operative blood loss and posterior spine fixation. **Design:** In This clinical trial, 78 patients in two groups of 39 people are studied. **Conduct:** With no prior knowledge, one group started to use volumetric ventilation with current volume 7ml/kg/IBW, 12 cycles per minute inspiration rate and inhale to exhale ratio 1:2 without peep, during the operation. The inspiration rate is altered to achieve end exhale carbon dioxide of 30-45 mmHg. The other group receives pressure ventilation with initial pressure 15 H2O/cm and 12 cycles per minute inspiration rate and inhale to exhale ratio 1:2 without peep. Then the current volume is adjusted to 7ml/kg/IBW by changing the pressure to achieve the end exhale carbon dioxide 35-40 mmHg by changing the inspiration rate. **Participations:** Among patients aged 18-75 in class1, 2 ASA, nominated for posterior spine fixation operation surgery were justified for the study and written consent derived from them. In this study patients with cardiopulmonary diseases history, uncontrolled hypertension or diabetes, SCI, coagulopathies, or treated by aspirin, heparin, and warfarin, and BMI more than 35 are omitted. **Interventions:** Blood pressure and heart beat of the studied patients are checked every 15 minutes after anesthesia. Then satisfaction of surgeon asked. **Main outcome:** Duration and intensity of bleeding are compared until the end of operations between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122731611N1**

Registration date: **2017-03-18, 1395/12/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-18, 1395/12/28

Registrant information

Name

Manoochehr Salimian

Name of organization / entity

Kashan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2016-10-01, 1395/07/10

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two ventilation methods "volume control & pressure control" on blood loss of posterior Spinal fixation surgery

Public title

Comparison of two ventilation methods "volume control & pressure control" on blood loss of posterior Spinal fixation surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 18-75 with physical condition scored 1 or 2 from American Anesthesia Association nominated for elective-fusion posterior spine surgery operation in 3-4 levels, hospitalized for traumatic fracture of the lumbar spine. Exclusion criteria: Patients with cardiopulmonary disorders; uncontrolled hypertension and diabetes; SCI and coagulopathies patients and patients with BMI more than 35; or treated by aspirin; heparin and warfarin are excluded from the study.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Ghotb-e-Ravandi Blvd, 5th Km, Kashan Road, 8715988141, Kashan, I. R. Iran

City

Kashan

Postal code

8715988141

Approval date

2016-09-28, 1395/07/07

Ethics committee reference number

IR.KAUMS.REC.1395.50

Health conditions studied

1

Description of health condition studied

Fracture of lumbar vertebra

ICD-10 code

S32.0

ICD-10 code description

Fracture of lumbar vertebra

Primary outcomes

1

Description

surgical blood loss

Timepoint

End of surgery

Method of measurement

Calculating the amount of blood in the suction drain and bleed by ml accumulat

Secondary outcomes

1

Description

Hypotension

Timepoint

During operation

Method of measurement

Continuous NIBP monitoring

2

Description

surgeon's satisfaction of a bloodless field

Timepoint

At the end of surgery

Method of measurement

surgeon's satisfaction scoring system

3

Description

Number of infused Blood bags

Timepoint

At the end of surgery

Method of measurement

Counting the number of infused blood bags

Intervention groups

1

Description

First group: during the surgery operation, volumetric ventilation was started with a current volume of 7 ml/kg/IBW, inspiration rate of 12 cycles per minute and inhale to exhale ratio of 1:2 without peep and the inspiration rate is changed to achieve exhale end carbon

dioxide of 35-40 mmHg.

Category

Treatment - Other

2

Description

Second group: during the surgery operation, pressure ventilation with the initial pressure of 15 H₂O/cm, inspiration rate of 12 cycles per minute and inhale to exhale ratio 1:2 with no peep drops down. Then the current volume will be achieved to 7 ml/kg/IBW by changing the pressure and the exhale end carbon dioxide will reach to 35-40 mmHg by changing the inspiration rate.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr. Manoochehr Salimian

Street address

Shahid Beheshti Hospital , Ghotb-e-Ravandi Blvd, 5th Km, Kashan Road, 8715988141, Kashan, I. R. Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology Kashan University of Medical Sciences

Full name of responsible person

GolamAli Hmidi MD.

Street address

Kashan University of Medical Sciences, Ghotb-e-Ravandi Blvd, 5th Km, Kashan Road, 8715988141, Kashan, I. R. Iran

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Kashan

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 and Technology Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Manoochehr Salimian

Position

Anesthesia resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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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