Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

The effect of Goal-directed fluid therapy on intraoperative transfusion rate in spine surgery in Golestan Hospital in 1399

Protocol summary

Study aim

The aim of this study was the effect of targeted fluid therapy on the rate of intraoperative transfusion in spine surgeries in Golestan Hospital in 1399.

Design

60 patients will be included in the study and will be divided into two groups of control and case (30 patients in each group) as simple parallel and randomized groups.researchers or analysts of the collected data will be blinded.

Settings and conduct

This double-blind clinical trial study is performed in Golestan Hospital, Ahvaz. Fluid therapy of patients in the case group will be based on hemodynamic parameters (changes in stroke volume) and in the control group, fluid therapy will be performed according to the standard protocol. researchers or analyzers of the collected data will not be informed of which group the patients belong to.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: age 18 to 70 years, candidate for spine surgery, absence of heart, kidney and liver disease, no use of anticoagulants. Exclusion criteria include: patient dissatisfaction, the Existence of pulmonary ral and crackle and pleural effusion

Intervention groups

For patients in the intervention group, targeted fluid therapy will be performed according to the protocol. Before induction, 4 mg/kg of crystalloid solution (Ringer) is given and then the hemodynamic invasive monitoring device will be installed through the radial artery, which is given crystalloid based on the variance of the impact volume of the therapeutic fluid. Patients in the control group will undergo conventional fluid therapy using the 1-2-2 mg / kg / h rule at a rate of 10 ml/kg/hr crystalloid (normal saline/Ringer serum).

Main outcome variables

Number of blood units required, bleeding rate, acidosis incidence, urinary output, vasopressor requirement, postoperative ventilator requirement and intraoperative crystalloid requirement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201014049024N1**
Registration date: **2020-11-09, 1399/08/19**
Registration timing: **retrospective**

Last update: **2020-11-09, 1399/08/19**
Update count: **0**

Registration date

2020-11-09, 1399/08/19

Registrant information

Name

sheida nassajian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3377 7966

Email address

nassajian.sh@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-21, 1399/02/02

Expected recruitment end date

2020-10-31, 1399/08/10

Actual recruitment start date

2020-04-22, 1399/02/03

Actual recruitment end date

2020-11-01, 1399/08/11

Trial completion date
2020-11-01, 1399/08/11

Scientific title
The effect of Goal-directed fluid therapy on intraoperative transfusion rate in spine surgery in Golestan Hospital in 1399

Public title
The effect of Goal-directed fluid therapy on intraoperative transfusion rate in spine surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 70 years Candidate for spine surgery No heart, kidney and liver disease Do not take anticoagulants

Exclusion criteria:
Patient dissatisfaction, Existence of pulmonary ral and crackle Existence of pleural effusion

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients who are candidates for spinal surgery will be selected by census according to the inclusion criteria and will be treated randomly using envelopes containing a code A (Targeted fluid therapy group) and B (Routine fluid therapy group).

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the double-blindness of the study, patients did not know whether they were in the routine or targeted fluid therapy group, and the recorder was unaware of whether the patients were in the study group or controls, and the statistical analyzer was unaware of the grouping and injection solution.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahwaz Jondishapour University Of Medical Sciences

Street address
Ethics Committee of Ahwaz Jondishapour University Of Medical Sciences, Golestan Blvd., Ahwaz

City
Ahvaz

Province
Khouzestan

Postal code
61357157941

Approval date
2020-06-16, 1399/03/27

Ethics committee reference number
IR.AJUMS.REC.1399.250

Health conditions studied

1

Description of health condition studied
Patients undergoing spinal surgery due to spinal canal stenosis or other causes.

ICD-10 code
M47

ICD-10 code description
Spondylosis

Primary outcomes

1

Description
Number of units of blood required

Timepoint
During surgery

Method of measurement
Number of injected blood bags

2

Description
Bleeding rate

Timepoint
During surgery

Method of measurement
Measurement of blood in suction, gas and blood clots

3

Description
Incidence of acidosis

Timepoint
During surgery

Method of measurement
Arterial blood gas testing

4

Description
Urinary output
Timepoint
During surgery
Method of measurement
The amount of urine in the bladder

5

Description
The need for a vasopressor
Timepoint
During surgery
Method of measurement
Number of vasopressor injections

6

Description
Need a ventilator after surgery
Timepoint
Immediately after surgery
Method of measurement
Need to use a ventilator after surgery

7

Description
Crystalloid requirements during surgery
Timepoint
During surgery
Method of measurement
Injectable serum volume

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For patients in the intervention group, targeted fluid therapy will be performed according to the protocol. Before induction, 4 mg / kg of crystalloid solution (Ringer) is given and then the hemodynamic invasive monitoring device will be installed through the radial artery, which is given crystalloid based on the variance of the impact volume of the therapeutic fluid.
Category
Prevention

2

Description
Control group: Patients in the control group will undergo conventional fluid therapy using the 4-2-2 mg / kg / h rule at a rate of 10 ml / kg / hr crystalloid (normal saline / Ringer serum).
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
Sheida Nassajain
Street address
Ahvaz., Golestan Blvd., Golestan hospital., Genera operating rooml
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8383
Email
nassajian.sh@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehdi Ahmadi Moghadam
Street address
Vice Chancellor For Research of Ahvaz Jundishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8383
Email
ahmadi-m@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Sheida Nassajian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8383
Email
Nassajian.sh@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Sheida Nassajian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8383
Email
Nassajian.sh@ajums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Sheida Nassajian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8383
Email
nassajian.sh@ajums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available