

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effects of goal-directed fluid therapy using LiDCOrapid system in postoperative outcomes and comparison with standard fluid therapy for patients undergoing spine surgery

Protocol summary

Study aim

Evaluation of effects of goal directed fluid therapy on reduction of postoperative outcomes in patients with spine surgery and and comparison with standard fluid therapy.

Design

After providing explanations about the goals of the research and obtaining informed consent 40 patients will be enrolled in this study. Two arm parallel group randomized trial (20 patients in each group). In order to blinding, the patients and Researcher and also statistical specialist who performs data analysis would not have any information about subjects in experimental and control groups.

Settings and conduct

Patients will randomly assign in case and control group. Fluid therapy in case group will be based on LidcoRapid hemodynamic monitor. Fluid therapy in the control group will be performed based on standard protocol. In order to blinding, the patients and Researcher and also statistical specialist who performs data analysis would be blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age greater than 18 Duration of operation more than 2 hours Ischemic heart disease Chronic obstructive pulmonary lung disease Hypertension Diabetes mellitus Exclusion Criteria: Patient refusal Irregular heart rhythm

Intervention groups

Case: Fluid therapy during surgery in this group was base on hemodynamic monitors such as stroke volume variation, cardiac output, Systemic vascular resistance and etc. Control: Fluid therapy during surgery in this group was based on standard protocol

Main outcome variables

Base excess Volume transfused Urine output (cc) Hospitalization (day) Intensive Care Unit admission (day) Starting solids (hour) Myocardial infarction Stroke

Pulmonary thromboembolism Deep vein thrombosis Pneumonia Pulmonary edema Urinary tract infection Sepsis Acute respiratory distress syndrome Acute renal failure Postsurgical nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190719044274N1**

Registration date: **2019-09-28, 1398/07/06**

Registration timing: **prospective**

Last update: **2019-09-28, 1398/07/06**

Update count: **0**

Registration date

2019-09-28, 1398/07/06

Registrant information

Name

Shervin Shahinpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8800 7624

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-11, 1398/07/19

Expected recruitment end date

2019-11-15, 1398/08/24

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of goal-directed fluid therapy using LiDCOrapid system in postoperative outcomes and comparison with standard fluid therapy for patients undergoing spine surgery

Public title
Goal directed fluid therapy in spine surgery

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 operations longer than 2 hours Ischemic heart disease
 Chronic obstructive pulmonary disease
Exclusion criteria:
 Patient refusal Irregular heart rhythm

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization After providing explanations about the goals of the research and obtaining informed consent, 40 patients undergoing Spine surgery will be selected with a simple random sampling method. Then they are divided into the case and control groups by simple randomization method.

Blinding (investigator's opinion)
Double blinded

Blinding description
people who were responsible for making assessments on postoperative outcomes or gathering data on outcome variables were blinded Also the people who analysed the data collected during this trial were blinded

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of the Tehran University of medical sciences

Street address

Keshavarz Blvd, Qods St, Tehran Town

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-05-30, 1398/03/09

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.115

Health conditions studied

1

Description of health condition studied

Patients with spine surgery due to Spinal canal stenosis, spondylopathies and etc with past medical history of Hypertension or Diabetes mellitus, Ischemic heart disease, Chronic obstructive pulmonary disease

ICD-10 code

M47

ICD-10 code description

Spondylosis

Primary outcomes

1

Description

Base excess

Timepoint

Before intervention and 1, 2, 3 hours after intervention

Method of measurement

Arterial blood gas

2

Description

Days of hospital stay

Timepoint

Days of hospital stay after surgery

Method of measurement

Reading the files and visiting patients

3

Description

Days of Intensive Care Unit stay

Timepoint

Days of Intensive Care Unit stay after surgery

Method of measurement

Reading the files and visiting patients

4

Description

postoperative nausea and vomiting

Timepoint

Nausea and vomiting after 12, 24 and 36 hours after surgery

Method of measurement

History Taking

5

Description

Pulmonary edema

Timepoint

Until 24 hours after surgery

Method of measurement

Chest Radiography and Physical examination

6

Description

Serum Transfusion

Timepoint

During Surgery

Method of measurement

Measurement of Serum given during surgery

7

Description

Oral intake Tolerance

Timepoint

24 hours after surgery

Method of measurement

History taking

Secondary outcomes

1

Description

Acute Respiratory Distress Syndrome

Timepoint

48 hours after surgery

Method of measurement

Chest Radiography, Blood gas analysis

2

Description

Pneumonia

Timepoint

48 hours after surgery

Method of measurement

Clinical manifestation and Chest radiography

3

Description

Myocardial infarction

Timepoint

48 hours after surgery

Method of measurement

Lab tests and Electrocardiography

4

Description

Hospital readmission

Timepoint

30 days after discharge

Method of measurement

Postoperative evaluation

5

Description

Urinary Tract Infection

Timepoint

48 hours after surgery

Method of measurement

Clinical manifestation, Urine analysis

Intervention groups

1

Description

Intervention group: Fluid therapy based on Hemodynamic Monitoring such as Stroke Volume Variation, Cardiac Output, Systemic Vascular Resistance and etc given by LidcoRapid Hemodynamic monitoring. Serum type will be crystalloid (lactated ringer)

Category

Treatment - Other

2

Description

Control group: In Control group fluid therapy would be based on standard protocols which is 4 cc/kg/h. If bleeding reaches to the maximum allowable blood loss blood transfusion will be started. Serum type will be crystalloid (lactated ringer).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Doctor Reza Shariat Moharari

Street address

Sina hospital, Hasan Abad Sqr, Tehran Iran

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Research Assistance of Tehran University of Medical Science

Street address

Central department of Tehran University of Medical Sciences, Qods st, Keshavarz Blvd, Tehran

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Dr Reza shariat Moharari

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

After completion of the study, if necessary, the encoded data will be published along with the article.

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

Yes - There is 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

Title and more details about the data/document

Abstract and references

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

Academic Researchers and Academic Institutes

Under which criteria data/document could be used

When referring to this research, mention the name of the researchers.

From where data/document is obtainable

Mailing address

What processes are involved for a request to access data/document

The applicant requests via email

Comments