**Clinical Trial Protocol**

**Iranian Registry of Clinical Trials**

27 Sep 2022

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**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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**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**
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

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
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
City
Tehran
Province
Tehran
Postal code
١١٩٦٤٧٦٣١١
Phone
+۹۸ ۲۱ ۶۶۳۴ ۸۵۰۰
Email
Moharari@tums.ac.ir

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

City
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Moharari@tums.ac.ir

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 updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Shervin Shahinpour

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
Hasan abad sq, Tehran , Sina Hospital

City
Tehran
Province
Tehran
Postal code

Person responsible for scientific 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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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