

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of fluid therapy based on plethysmographic Variability Index (PVI) and conventional method in spontaneous breathing patients on postoperative lactate levels in patients undergoing cesarian section surgery under spinal anesthesia

Protocol summary

Summary

Objectives: This study investigates the variability in the Pleth Variability Index on fluid management and correlation with lactate levels in patients candidate for cesarean section surgery. **Design:** This single centered randomized clinical trial is conducted on 70 patients who are candidate for cesarean section. **Setting and Conduct:** This study is taken place at Shariati hospital operating theater between April 2015 and April 2016. **Participants:** 70 pregnant women candidates for cesarean section delivery **Intervention:** The patients are randomly assigned to one of the Pleths variability index or conventional groups. Arterial blood sample is extracted and sent to laboratory to measure serum lactate level. 5 cc/kg crystalloid fluid is infused as the bolus, spinal anesthesia is induced and then in group A: 2cc/kg/hour of fluid is maintained, once PVI > 13 %, a 250 mL crystalloid is rapidly infused and repeated for every 5 minutes up to three times. In group B: 4-8 mL/kg/h crystalloid fluid infusion is maintained, and quick fluid infusion is initiated if mean arterial blood pressure (MAP) < 65 mmHg. In both groups, 10 mg ephedrine is given to keep mean arterial BP above 65 mmHg as needed. **Outcome measures:** 1) the serum level of lactate on admission as well as at the end of surgery, 2) mean arterial pressure before anesthesia as well as 1, 2, 3, and 5 minutes after that, 3) the total amount of intraoperative fluids infused, 4) the amount of urine output within surgery, and 5) the duration of surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010525856N1**
Registration date: **2017-01-14, 1395/10/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-14, 1395/10/25

Registrant information

Name

Siyamak Tavakoli

Name of organization / entity

Tehran Univercity

Country

Iran (Islamic Republic of)

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+98 913 326 3724

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s_tavakoli@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of fluid therapy based on plethysmographic Variability Index (PVI) and conventional method in

spontaneous breathing patients on postoperative lactate levels in patients undergoing cesarian section surgery under spinal anesthesia

Public title

Fluid therapy in pregnancy in cesarian section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 18 to 50 years; American Society of anesthesiologists physical status class I and II; A body mass index (BMI) less than 30 kilograms per cubic meter. Exclusion criteria: History of systemic (cardiovascular, renal, hepatic, or vascular) disorders; Need to planned pharmacologic or mechanical cardiovascular manipulation; Needing repeated blood sampling; Failure of indirect arterial blood pressure measurement; Supplementary diagnostic information from the arterial waveform; Needing central venous pressure monitoring; Needing pulmonary artery catheterization and monitoring; Requiring transvenous cardiac pacing; Needing temporary hemodialysis; Need to aspirate air emboli; Inadequate peripheral intravenous access; Prolonged surgery (longer than 3 hours);

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

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

Ethic committee, Faculty of medicine of Tehran
University of Medical Sciences

Street address

Research deputy, Ethics Committee of Tehran
University of Medical Sciences, 6th floor, Tehran
University of Medical Sciences building, Ghods St,

Keshavarz Blvd

City

Tehran

Postal code

Approval date

2015-06-08, 1394/03/18

Ethics committee reference number

IR.TUMS.REC.1394.1597

Health conditions studied

1

Description of health condition studied

Abnormal blood-pressure reading, without diagnosis

ICD-10 code

R03

ICD-10 code description

Abnormal blood-pressure reading, without diagnosis

Primary outcomes

1

Description

Total amount of intraoperative fluids infused after fluid therapy according to plethysmographic variability index (PVI)

Timepoint

End of surgery

Method of measurement

Milliliter

2

Description

Amounts of lactate in fluid therapy according to PVI (plethysmographic variation Index)

Timepoint

On admission as well as at the end of surgery

Method of measurement

Millimole/liter , Enzymatic

3

Description

Mean arterial pressure during fluid therapy according to PVI (plethysmographic variation index)

Timepoint

before anesthesia as well as 1, 2, 3, and 5 minutes after that

Method of measurement

Using patients monitoring - millimeter of mercury

4

Description

Total amounts of Urine output after fluid therapy according to PVI (plethysmographic variation index)

Timepoint

End of surgery

Method of measurement

Milliliter

Secondary outcomes

1

Description

Total amount of intraoperative fluids infused after fluid therapy according to conventional method

Timepoint

End of surgery

Method of measurement

Milliliter

2

Description

Amounts of lactate in fluid therapy according to conventional method

Timepoint

on admission as well as at the end of surgery

Method of measurement

Millimole/liter, Enzymatic

3

Description

Mean arterial pressure during fluid therapy according to conventional method

Timepoint

Before anesthesia as well as 1, 2, 3, and 5 minutes after that

Method of measurement

Using patients monitoring - millimeter of mercury

4

Description

Total amounts of Urine output after fluid therapy according to conventional method

Timepoint

End of surgery

Method of measurement

Milliliter

Intervention groups

1

Description

5 cc/kg crystalloid fluid is infused as the bolus, spinal anesthesia is induced and then 2cc/kg/hour of fluid is maintained, once PVI > 13 %, a 250 mL crystalloid is rapidly infused and repeated for every 5 minutes up to three times.

Category

Treatment - Other

2

Description

5 cc/kg crystalloid fluid is infused as the bolus, spinal

anesthesia is induced and then 4-8 mL/kg/h crystalloid fluid infusion is maintained

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati Hospital

Full name of responsible person

Dr. Siamak Tavakoli

Street address

Dr. Shariati Hospital, North Kargar Ave, Amirabad
Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhoondzadeh

Street address

Vice Chancellor for research, Tehran University of
Medical Sciences Tehran Tehran Iran, Islamic Republic
Of Tehran

City

Tehran

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

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

Dr. Shariati Hospital

Full name of responsible person

Dr. Siamak Tavakoli

Position

Resident of Anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Dr. Reza Atef Yekta

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Professor of Anesthesiology

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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