

# 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)

###### Phone

+98 913 326 3724

###### Email address

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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S\_tavakoli@razi.tums.ac.ir

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Dr. Reza Atef Yekta

**Position**

Professor of Anesthesiology

**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*