

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Comparison of the effect of fluid therapy based on plethysmographic Variability Index (PVI) and conventional method on postoperative lactate levels in patients undergoing thyroidectomy surgery

#### Protocol summary

##### Summary

**Objectives:** This study investigates the variability in the Pleth Variability Index on fluid management and correlation with lactate levels. **Design:** Single centered randomized clinical trial. **Setting and Conduct:** This study is taken place at Shariati hospital operating theater between April 2017 and September 2017. **Participants:** 50 patients candidate for elective thyroidectomy **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. General anesthesia is induced and then in group A: 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 . **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.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201410285140N14**  
Registration date: **2017-04-19, 1396/01/30**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-04-19, 1396/01/30

#### Registrant information

##### Name

Omid Azimaraghi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2206 6194

##### Email address

cazimaraghi@tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran University of Medical Sciences

#### Expected recruitment start date

2017-05-05, 1396/02/15

#### Expected recruitment end date

2017-07-21, 1396/04/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the effect of fluid therapy based on plethysmographic Variability Index (PVI) and conventional method on postoperative lactate levels in patients undergoing thyroidectomy surgery

#### Public title

Fluid therapy in Thyroidectomy Surgery

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 18 to 60 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; Inadequate peripheral intravenous access; Prolonged surgery (longer than 3 hours);intraoperative dysrhythmias;

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **50**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

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 Tehran Iran, Islamic Republic Of

##### City

Tehran

##### Postal code

#### Approval date

2016-10-29, 1395/08/08

#### Ethics committee reference number

IR.TUMS.VCR.REC.1395.879

## Health conditions studied

### 1

#### Description of health condition studied

Fluid Therapy

#### ICD-10 code

R83-R89

#### ICD-10 code description

Abnormal findings on examination of other body fluids, substances and tissues, without diagnosis

## Primary outcomes

### 1

#### 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

## 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

In group A: During surgery once PVI > 13 %, a 250 mL crystalloid is infused and repeated for every 5 minutes up to three times.

#### Category

Treatment - Drugs

### 2

#### Description

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.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shariati Hospital

##### Full name of responsible person

Dr. Ali Movafegh

##### Street address

Dr. Shariati Hospital, North Kargar Ave, Amir Abad

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor of research-Faculty of Medicine-  
Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Shahin Akhoondzadeh

##### Street address

Tehran University of Medical Sciences, Poorsina street  
,Keshavarz avenue,

##### City

Tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice chancellor of research-Faculty of Medicine-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

Professor of Anesthesiology, Dr shariati Hospital

##### Full name of responsible person

Dr Ali Movafegh

##### Position

Full Professor

##### Other areas of specialty/work

##### Street address

Dr. Shariati Hospital, North Kargar Ave, Amir Abad,  
Tehran

##### City

Tehran

##### Postal code

##### Phone

+98 21 8490 2282

##### Fax

##### Email

movafegh@sina.tums.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Department of Anesthesiology, Tehran University of  
Medical Sciences

##### Full name of responsible person

Dr Ali Movafegh

##### Position

Full Professor

##### Other areas of specialty/work

##### Street address

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

Dr Shariati Hospital

##### Full name of responsible person

Omid Azimaraghi

**Position**

Assistant Professor of Anesthesiology

**Other areas of specialty/work****Street address**

Dr. Shariati Hospital, North Kargar Ave, Amir Abad,  
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**Web page address****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*