

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

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

#### Protocol summary

##### Study aim

Compare the changes in intraoperative serum lactate levels with plethysvariability index guided intraoperative fluid therapy in comparison to the conventional approach

##### Design

Pleths and conventional group, parallel group, single blind

##### Settings and conduct

Operating room

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 18–65 years American Society Anesthesiology class I,II Elective Thyroidectomy Surgery Exclusion Criteria: Cardiac arrhythmia Lung diseases Intraoperative bleeding was >300 mL Duration of surgery was >3 hours

##### Intervention groups

In the Pleths group, 5 cc/kg bolus of normal saline was administered prior to anesthesia and continuous crystalloid infusion using 2 mL/kg/h of normal saline was administered throughout the surgery. If the PVI was >13% for 5 min, a 100 mL bolus of normal saline was administered and repeated until the PVI reached 13%. In the conventional group, 5 cc/kg bolus of normal saline was administered prior to anesthesia induction and continuous crystalloid infusion (5 mL/kg/h) was administered throughout the surgery.

##### Main outcome variables

Serum Lactate Levels

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150929024268N3**

Registration date: **2018-10-03, 1397/07/11**

Registration timing: **retrospective**

Last update: **2018-10-03, 1397/07/11**

Update count: **0**

##### Registration date

2018-10-03, 1397/07/11

##### Registrant information

###### Name

omid azimaraghi

###### Name of organization / entity

Department of Anesthesia

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8490 2436

###### Email address

o-azimaraghi@sina.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2017-12-23, 1396/10/02

##### Expected recruitment end date

2018-05-22, 1397/03/01

##### Actual recruitment start date

2017-05-23, 1396/03/02

##### Actual recruitment end date

2018-05-22, 1397/03/01

##### Trial completion date

2018-05-22, 1397/03/01

##### Scientific title

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

##### Public title

Intraoperative Fluid therapy

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients aged 18–65 years American Society Anesthesiology class I,II Elective Thyroidectomy Surgery

### Exclusion criteria:

Cardiac arrhythmia Lung diseases Intraoperative bleeding was >300 mL Duration of surgery was >3 hours

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **50**

Actual sample size reached: **46**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Prepared computer-based randomization

## Blinding (investigator's opinion)

Not 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

##### City

Tehran

##### Province

Tehran

##### Postal code

14155-6559

#### 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

E87.8

#### ICD-10 code description

Other disorders of electrolyte and fluid balance, not elsewhere classified

## Primary outcomes

### 1

#### Description

Serum Lactate

#### Timepoint

Before Anesthesia and at the end of surgery

#### Method of measurement

blood sample

## Secondary outcomes

### 1

#### Description

Amount of fluid

#### Timepoint

From before anesthesia and till the end of anesthesia

#### Method of measurement

millimeters

## Intervention groups

### 1

#### Description

Intervention group: In the Pleths group, 5 cc/kg bolus of normal saline was administered prior to anesthesia and continuous crystalloid infusion using 2 mL/kg/h of normal saline was administered throughout the surgery. If the PVI was >13% for 5 min, a 100 mL bolus of normal saline was administered and repeated until the PVI reached 13%.

#### Category

Other

### 2

#### Description

Control group: In the conventional group, 5 cc/kg bolus of normal saline was administered prior to anesthesia induction and continuous crystalloid infusion (5 mL/kg/h) was administered throughout the surgery.

#### Category

Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Shariati Hospital, Tehran University of Medical Sciences

**Full name of responsible person**

Omid Azimaraghi

**Street address**

Dr. Shariati Hospital, North Kargar Ave, Amirabad  
Tehran

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1411713135

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+98 21 8490 2282

**Email**

o.azimaraghi@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Shahin Akhoondzadeh

**Street address**

Dr. Shariati Hospital, Jalal-Al-Ahmad, Kargar Ave.,  
Tehran, Iran

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**Email**

dralimovafegh@gmail.com

**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**

Ali Movafegh

**Position**

Full Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Omid Azimaraghi

**Position**

Assistant Professor of Anesthesiology

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Email**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All collected deidentified data sets are to be shared

**When the data will become available and for how long**

Starting 6 months after publication

**To whom data/document is available**

only available for people working in academic institutions

**Under which criteria data/document could be used**

If the source is mentioned its allowed to use data.

**From where data/document is obtainable**

Email to corresponding author:

dralimovafegh@gmail.com

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

Email to corresponding author and the access will be granted in less than a month

**Comments**