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 plethsvariability 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)

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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
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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

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Dr. Shariati Hospital, North Kargar Ave, Amirabad Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Shahin Akhoondzadeh

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

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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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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