Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Evaluation of Goal Directed Fluid Therapy (GDFT) through Pleth Variability Index(PVI) in Plastic Surgery based on Enhanced Recovery After Surgery(ERAS)

Protocol summary

Study aim

Comparison of Goal Directed fluid therapy (GDFT) through Plethysmographic Variability Index (PVI) in plastic surgeries based on the Accelerated Recovery of Patients After Surgery (ERAS) protocol.

Design

A clinical trial with a control group, with parallel groups, randomized, on 72 patients

Settings and conduct

In patients undergoing surgery (abdominoplasty, mammoplasty) in the plastic department of Sina Hospital, comparing targeted fluid therapy based on the PVI index and the Traditional method, a double-blind randomized trial, in which the researcher and the patient were blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People over 18 years of age and without a history of specific diseases, who refer to Sinai Hospital for plastic and cosmetic surgeries such as abdominoplasty, mammoplasty, and facelift, will be included in the study. Exclusion criteria: people who are undergoing surgeries other than cosmetic or day care surgeries, patients under 18 years old, people with a history of underlying diseases, patients with cardiac arrhythmia, cardiac ejection fraction ≤30% , pulmonary diseases interfering with mechanical ventilation and patients with chronic kidney failure and patients who experience massive bleeding during surgery that requires blood transfusion, the duration of the operation will not be less than 2 hours will not be included in the study.

Intervention groups

The intervention group (36 patients) includes targeted fluid therapy (GDFT) based on the PVI index with the aim of keeping the index below 13%. The control group (36 patients) includes patients whose fluid therapy is traditional during the operation (4cc/Kg/h).

Main outcome variables

effect of fluid therapy; pain; nausea and vomiting; fatigue and sleepiness; constipation; tendency to discharge; wound site infection; wound site dehisence comparing the intervention group with the control group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210508051226N1**
Registration date: **2022-10-25, 1401/08/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-25, 1401/08/03**
Update count: **0**

Registration date

2022-10-25, 1401/08/03

Registrant information

Name

Nazli Ebrahimian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8500

Email address

nazli.ebrahimian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-22, 1401/07/30

Expected recruitment end date

2023-01-05, 1401/10/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Goal Directed Fluid Therapy (GDFT) through Pleth Variability Index(PVI) in Plastic Surgery based on Enhanced Recovery After Surgery(ERAS)

Public title
Fluid therapy in plastic surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
With no history of specific diseases that are referred for plastic and cosmetic surgeries such as abdominoplasty, mammoplasty and lift
Exclusion criteria:
Surgeries other than cosmetics and plastic surgery Outpatient cosmetic surgeries History of heart disease (cardiac arrhythmia, cardiac ejection fraction ≤30%) History of lung disease interfering with mechanical ventilation History of chronic kidney failure
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method is based on blocking quadruple numbers. Variable blocks will be used for randomization, which is due to the ease of execution and the balance in the number of groups. In this way, the samples will be divided into A and B, and there will be six cases for the four blocks and the cards are replaced based on the number of samples
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding in this study is a two-way blind type. In this way, all the patients included in the study are unaware of being in the control or intervention arm (blind). On the other hand, the outcome assessor (primary and secondary) and the data analyzer They are blinded to the intervention and control groups. Due to the sensitivity of patient care during surgery and the absence of harm to the patients, the clinical caregiver (researcher) was not blinded to the intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
sina hospital ethic committee
Street address
sina hospital, hassanabad square imam khomeini street
City
Tehran
Province
Tehran
Postal code
۱۱۳۶۷۴۶۹۱۱
Approval date
2021-04-21, 1400/02/01
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1400.011

Health conditions studied

1

Description of health condition studied
Plastic and cosmetic surgeries such as abdominoplasty, mammoplasty and lift
ICD-10 code
Z41.1
ICD-10 code description
Other plastic surgery for unacceptable cosmetic appearance

Primary outcomes

1

Description
Comparison of targeted fluid therapy (GDFT) through Plethysmographic Variability Index (PVI) in plastic surgeries based on rapid recovery protocol for patients after surgery (ERAS)
Timepoint
during surgery period
Method of measurement
Through plethysmographic variability index (PVI) using pulse oximeter

Secondary outcomes

1

Description
pain severity
Timepoint
daily after surgery
Method of measurement
Visual Analogue Score

2

Description
post operative nausea and vomiting
Timepoint
daily after surgery
Method of measurement
Questionnaire

3

Description
surgical site infection
Timepoint
Day 1-3-7-28 after surgery
Method of measurement
physician observation

4

Description
drowsiness and fatigue
Timepoint
daily after surgery
Method of measurement
Questionnaire

5

Description
constipation
Timepoint
daily after surgery
Method of measurement
questionnaire

6

Description
renal function
Timepoint
day 1-2 afyter surgery
Method of measurement
measuring serum creatinine

7

Description
Pulmonary function
Timepoint
daily after surgery
Method of measurement
Questionnaire

8

Description
Desire for early discharge
Timepoint
after surgery
Method of measurement
Questionnaire

9

Description
wound dehiscence
Timepoint
daily after surgery
Method of measurement
physician observation

Intervention groups

1

Description
Intervention group:36 patients are done fluid therapy (GDFT) based on PVI index. These patients are hospitalized the night before the operation and will be allowed to consume solid food 6 hours before the operation and clear and carbohydrate-rich liquids 2 hours before the operation. Fluid therapy in this group is prescribed based on the information obtained from the PVI with The goal is to keep the index under 13%. After transferring the patients to the surgical department, the patients in terms of the number of times they experienced nausea, vomiting, fever, constipation, the duration of fasting after the operation, the amount of receiving painkillers and antiemetics, the length of hospitalization Willingness to early discharge, surgical site infection, dehiscence, wound SSI, creatinine levels before or after surgery to check kidney function and pulmonary complications will be evaluated and the information will be entered into the questionnaire.
Category
Treatment - Surgery

2

Description
Control group: 36 patients, which includes the group of patients whose fluid therapy is traditional, in this group, pre-operative fluid therapy will be such that the patient is hospitalized one night before the operation and receives one liter of serum, and the patient 8 hours before He becomes NPO from the operation. In this group, fluid therapy during the operation is 4cc/Kg/h and the patient is NPO after the operation until full consciousness.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital

Full name of responsible person
Nazli Ebrahimian

Street address
Sina hospital,Emam khomeini st.,Hassan abad sq.,

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Province
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1136746911

Phone
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Email
hosp_sina@sina.tums.ac.ir

Web page address
https://sinahospital.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr.Akbar Fotouhi

Street address
Ghods St., Porsina St., North Door of University, Building No. 1

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Phone
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Email
okazi@tums.ac.ir

Web page address
http://medicine.tums.ac.ir/med/med

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
Nazli Ebrahimian

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
SPSS data file that includes demographic information, primary outcome and secondary outcomes
When the data will become available and for how long
Immediately after the publication of the article
To whom data/document is available
Academic and scientific researchers
Under which criteria data/document could be used
Allowance of any analysis for the data
From where data/document is obtainable
corresponding author
What processes are involved for a request to access data/document
E-mailing the corresponding author
Comments