

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 $\leq 30\%$, 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 dehiscence 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 $\leq 30\%$)
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

1136746911

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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Phone

+98 21 6634 8500

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

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 6405 3334

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 scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Nazli Ebrahimian

Position

Resident

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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