Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the effect of different doses of intravenous dextrose solution administered intraoperatively on incidence and severity of postoperative nausea and vomiting in patients undergoing rhinoplasty surgery (A randomized controlled trial)

Protocol summary

Study aim
Comparison of the effect of injecting different doses of intravenous dextrose solution intraoperatively on the incidence and severity of postoperative nausea and vomiting in rhinoplasty patients.

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 144 patients. Random Allocation software is used for randomization.

Settings and conduct
Injection of different doses of dextrose solution (containing 25 grams and 50 grams of glucose in the two intervention groups) and comparing it with placebo injection (containing ringer lactate in the control group) and together, in patients undergoing rhinoplasty at Amir al-Momenin Hospital in Rasht. Participants and outcome assessors do not know the nature of the injection solution.

Participants/Inclusion and exclusion criteria
Entry requirements: Female patients aged 18 to 65 undergoing rhinoplasty Non-entry conditions: History of underlying diseases such as diabetes, heart, liver and kidney failure and history of sensitivity to the anesthetics of study

Intervention groups
There are two intervention groups. Both intervention groups, like the control group, receive 5 mL/kg of ringer lactate serum as CVE and receive maintenance serum during surgery (40 mL for the first 10 kg per hour, 20 mL for the second 10 kg per hour and for each subsequent 1 kg per hour, 1 mL) are placed; with the difference that intervention group 1 receives 500 mL of D5 solution (containing 25 g of glucose) and intervention group 2 receives 500 mL of D10 solution (containing 50 g of glucose) in addition to the same serums described above. The total serum will be injected.

Main outcome variables
Incidence and severity of nausea and vomiting based on Visual analog nausea score criteria, immediately, 30 minutes, 60 minutes, 90 minutes, 3 hours, 6 hours, 12 hours and 24 hours after entering the ward.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20131228015963N10**
Registration date: **2023-12-23, 1402/10/02**
Registration timing: **prospective**

Last update: **2023-12-23, 1402/10/02**
Update count: **0**

Registration date
2023-12-23, 1402/10/02

Registrant information

Name
Soudabeh Haddadi

Name of organization / entity
Guilan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2024-01-10, 1402/10/20

Expected recruitment end date

2024-07-10, 1403/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of different doses of intravenous dextrose solution administered intraoperatively on incidence and severity of postoperative nausea and vomiting in patients undergoing rhinoplasty surgery (A randomized controlled trial)

Public title

Comparison of the effect of different doses of intravenous dextrose solution on incidence and severity of postoperative nausea and vomiting

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Female patients aged 18 to 65 undergoing rhinoplasty Patients who are candidates for rhinoplasty surgery Patients in ASA I and ASA Ⅱ class

Exclusion criteria:

History of diabetes mellitus (DM) Known congestive heart failure (CHF) Pregnant women Recent opioid use (within 48 hours before surgery) Having a history of postoperative nausea and vomiting (PONV) or motion sickness Smoker patients Known renal or hepatic failure or impaired preoperative tests Patients who have used anti-nausea medication 24 hours before surgery. Patients who have abnormal blood sugar on the morning of surgery. (Blood sugar more than 125 mg/dL) Known sensitivity to anesthetics used in the study

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

This research involves a randomized controlled trial of the equivalence type with a parallel study design. To allocate patients to intervention and control groups, we will utilize the approach of restricted randomization (block randomization) in parallel, considering blocks randomly with a size of 6. The generation of random numbers will be facilitated using a random number table (Random Allocation software). Allocation concealment will be employed to conceal and manage confounding factors. This method ensures the implementation of a random sequence for participant allocation in the study, thereby not specifying the assigned group before individual assignment. This method involves the use of sealed envelopes, each containing a recorded random sequence card. These cards are arranged within the envelopes in a specific order, with the outer surface of the envelopes numbered accordingly. During the registration of eligible patients for the study, one of the envelopes will be opened sequentially, determining whether the patient will receive different doses of intravenous dextrose solution or be placed in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is conducted in a double-blind manner, which includes participants and outcome assessors. In both the intervention and control groups, blinding will be done completely, the syringes and materials of the intervention and placebo will be the same in terms of color. Blinding will be done on injectable serums and syringes with specified codes. The outcome assessors also do not know the nature of the injection solution.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Guilan University of Medical Sciences

Street address

Amir Al Mo’menin Hospital - 17th Shahrivar St. - Hafez Boulevard - Rasht - Gilan – Iran

City

Rasht

Province

Guilan

Postal code

3845941396

Approval date

2023-11-15, 1402/08/24

Ethics committee reference number

IR.GUMS.REC.1402.426

Health conditions studied

1

Description of health condition studied
Postoperative nausea and vomiting
ICD-10 code
R11.2
ICD-10 code description
تهوع و استفراغ بعد از عمل (Postoperative nausea and vomiting)

Primary outcomes

1

Description
Comparison of the effect of different doses of intravenous dextrose solution administered intraoperatively on incidence and severity of postoperative nausea and vomiting
Timepoint
The incidence and severity of postoperative nausea and vomiting, based on the Visual analog nausea score, will be measured and recorded by nurses immediately, 30 minutes, 60 minutes, 90 minutes, 3 hours, 6 hours, 12 hours and 24 hours after entering the ward. In case of discharge in less than 24 hours, during a phone call, the patient's nausea and vomiting will be recorded, as well as the amount of anti-nausea medication (in the amount of 4 mg of intravenous and oral ondansetron during hospitalization or after discharge in case of vomiting). The duration of recovery will be recorded in all three groups. Also, blood sugar will be checked and recorded immediately, 30 minutes, 60 minutes, 90 minutes, 3 hours, 6 hours, 12 hours and 24 hours after the operation (if there is no glucose intolerance and the patients are discharged , blood sugar measurement will be stopped). An increase in blood sugar to more than 200 mg/dL will require intervention. The intervention method is the injection of 1 unit of short-acting insulin (like regular insulin) for every 25 mg/dL increase in blood sugar greater than 200 mg/dL.
Method of measurement
Incidence and severity of nausea and vomiting (PONV), based on Visual analog nausea score criteria, immediately, 30 minutes, 60 minutes, 90 minutes, 3 hours, 6 hours, 12 hours and 24 hours after entering the ward, need for anti-inflammatory drugs Nausea (the amount consumed after 24 hours) of the patients and the duration of hospitalization are recorded according to a questionnaire that will be designed by the researcher.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Like the control group, will receive 5 mL/kg of ringer lactate serum as compensatory intravascular volume expansion (CVE) and maintenance serum during surgery (40 mL for the first 10 kg per hour, 20 mL for the second 10 kg per hour and for each subsequent 1 kg per hour, 1 mL); with the difference that intervention group 1 will receive 500 mL of D5 solution (containing 25 g of glucose) in addition to the same serums described above. The total serum will be injected from the start of anesthesia to the patients of this group for 60 minutes.
Category
Prevention

2

Description
Intervention group 2: Like the control group, will receive 5 mL/kg of ringer lactate serum as compensatory intravascular volume expansion (CVE) and maintenance serum during surgery (40 mL for the first 10 kg per hour, 20 mL for the second 10 kg per hour and for each subsequent 1 kg per hour, 1 mL); with the difference that intervention group 2 will receive 500 mL of D10 solution (containing 50g of glucose) in addition to the same serums described above. The total serum will be injected from the start of anesthesia to the patients of this group for 60 minutes.
Category
Prevention

3

Description
Control group: Will receive 5 mL/kg ringer lactate serum as compensatory intravascular volume expansion (CVE) and receive maintenance serum during surgery (40 mL for the first 10 kg per hour, 20 mL for the second 10 kg per hour, and 1 mL for each subsequent 1 kg per hour) like other groups. And unlike the two intervention groups, they will receive 500 mL of ringer lactate in addition to the above serums. The total serum will be injected to the patients of this group for 60 minutes from the start of anesthesia.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Al Mo'menin Hospital in Rasht
Full name of responsible person
Alireza Mofid Nakhaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Shahid beheshti Highway - Rasht - Gilan - 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
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Alireza Mofid Nakhaei
Position
Medical student
Latest degree
A Level or less
Other areas of specialty/work
Medical Education
Street address
Amir Al Mo'menin Hospital - 17th Shahrivar St. - Hafez Boulevard - Rasht - Gilan – Iran
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is 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
Demographic characteristics of participants that affect outcomes and the type of intervention and outcomes are shared.
When the data will become available and for how long
The access period starts 3 months after the results are published
To whom data/document is available
Researchers and people who are engaged in the clinical field under study can apply for them.
Under which criteria data/document could be used
Researchers who are engaged in the clinical field of study can apply to receive them.
From where data/document is obtainable
Project implementers in Amir al-Momenin Hospital in Rasht Doctor Soodabeh Haddadi so_haddadi@gums.ac.ir Alireza Mofid Nakhaei alireza.mofidnakhaei@gmail.com
What processes are involved for a request to access data/document
The request for project data and information should be done in coordination with the project implementers.
Comments