Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Postoperative nausea and vomiting prevalence in patients with routine NPO and NPO with clear fluids 2 hours before cataract surgery

Protocol summary

Study aim
Comparison of Postoperative nausea and vomiting prevalence in patients with routine NPO and NPO with clear fluids 2 hours before cataract surgery

Design
This study will be conducted as a randomized clinical trial (blocks of four), double-blind, with parallel groups, without a control group, with the participation of 80 patients.

Settings and conduct
This study is a randomized clinical trial (blocks of four), double-blind (participants and results analyzer), with parallel groups, without a control group and with the participation of 80 cataract surgery candidates referred to Imam Reza Hospital (Tabriz) will be done.

Participants/Inclusion and exclusion criteria
The criteria for entering the study include: ASA class I and II , candidates for cataract surgery and consent to participate in the study, and the exclusion criteria are: having diabetes or other endocrine disorders, using antiemetics in the last 24 hours, Positive history of motion sickness or PONV and patients with Crohn's disease.

Intervention groups
Patients in the intervention group can eat clear liquids up to two hours before anesthesia, while patients in the control group will not eat anything from eight hours before anesthesia.

Main outcome variables
Nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190325043107N36**
Registration date: **2023-10-22, 1402/07/30**
Registration timing: **prospective**

Last update: **2023-10-22, 1402/07/30**
Update count: **0**

Registration date
2023-10-22, 1402/07/30

Registrant information

Name
Mehdi Khanbabayi Gol

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3334 7054

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khanbabayimehdi69@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-05, 1402/08/14

Expected recruitment end date
2023-12-19, 1402/09/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Postoperative nausea and vomiting prevalence in patients with routine NPO and NPO with clear fluids 2 hours before cataract surgery

Public title

Postoperative nausea and vomiting prevalence in patients with routine NPO and NPO with clear fluids 2 hours before surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

American Standards Association(ASA)class I and II Candidate for cataract surgery Consent to participate in the study

Exclusion criteria:

Having diabetes or other endocrine disorders Use of antiemetics in the last 24 hours Positive history of motion sickness or Postoperative nausea and vomiting(PONV) Patients with Crohn's disease

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, with a sample size of 80, we use the patients using the block permutation randomization method, which is used in this method to balance the number of allocated samples, and with 4 people in each block. We assemble the possible blocks as follows. block 1: BBAA, block 2: AABB, block 3: ABAB, block 4: BABA, block 5: ABBA, and block 6: BAAB, we need 20 blocks for 80 people. It is random in the block method. We choose numbers from one to six. For example, if number 6 is chosen as the first block and number 2 as the second block, the people who enter the study will be given BAABAABB in order from left to right. and finally they were divided into two intervention groups (group A) and control group (group B).

Blinding (investigator's opinion)

Double blinded

Blinding description

The thesis results analyst who analyzed the expected outcome and also the participants remained unaware of the type of procedure performed and were blind during the study; Therefore, this study was conducted in a double-blind manner.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

IR.TBZMED.REC.1402.4

Approval date

2023-10-18, 1402/07/26

Ethics committee reference number

IR.TBZMED.REC.1402.527

Health conditions studied

1

Description of health condition studied

Nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Nausea and vomiting

Timepoint

Once every hour and for six hours after the end of anesthesia

Method of measurement

Clinical observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cataract surgery candidates can drink clear liquids up to two hours before anesthesia. Then the patients will be anesthetized and undergo surgery. Nausea and vomiting after anesthesia will be recorded up to six hours and once every hour.

Category

Prevention

2

Description
Control group: Cataract surgery candidates can drink clear liquids up to eight hours before anesthesia. Then the patients will be anesthetized and undergo surgery. Nausea and vomiting after anesthesia will be recorded up to six hours and once every hour.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Mehdi Nazari
Street address
Imam Reza Hospital, Azadi Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Mehdi Khanbabayi Gol
Position
MSc in Nursing Education
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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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