

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Investigating The effect of peppermint oil on nausea, vomiting and post-operative pain in patients undergoing Rhinoplasty surgery: A Randomized Controlled Trial

#### Protocol summary

##### Study aim

Investigating the effect of peppermint essential oil on nausea, vomiting and postoperative pain in patients undergoing rhinoplasty at the Amirul Mominin Research and Training Center in Rasht.

##### Design

64 eligible patients are continuously selected. Online software (<https://www.randomizer.org/>) will be used for random allocation of samples in two groups. Sample size required to investigate the effect of mint essential oil on nausea, vomiting and pain in patients undergoing rhinoplasty surgery based on the results. The study of Maggi et al. with the nausea severity score equal to  $4.61 \pm 2.85$  and  $2.43 \pm 2.84$  in the control and intervention groups, respectively, in the first 4 hours after the operation, considering the test power of 80% and error The first type of 5% based on the following relationship, the number of 28 people in each group and taking into account 10% attrition, the volume of samples in each group equal to 32 qualified people was continuously determined.

##### Settings and conduct

Demographic information questionnaire is used to collect data and to investigate vomiting through observation and evaluation of nausea according to nursing reports and patients' statements, as well as VAS scale for pain. This study is carried out in Amir al-Mominin Teaching Hospital.

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1- Being at least 18 years old and at most 65 years old; not having a smell problem 3-under elective rhinoplasty and septorhinoplasty surgery; 4- Not having an allergy to mint; 5- No smoking and drug use; 6- Patients in class (ASA (I, II)); 7- Not breastfeeding; Exclusion criteria 1- Failure to comply with the desired anesthesia protocol; 2- Receiving anti-nausea medication before or during anesthesia; 3- Unwillingness

to cooperate

##### Intervention groups

Peppermint essential oil

##### Main outcome variables

Nausea and vomiting and pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210927052608N2**

Registration date: **2023-04-28, 1402/02/08**

Registration timing: **prospective**

Last update: **2023-04-28, 1402/02/08**

Update count: **0**

##### Registration date

2023-04-28, 1402/02/08

##### Registrant information

##### Name

reza pourmohammad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 4366 4045

##### Email address

r\_pourmohammad@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-27, 1402/03/06

##### Expected recruitment end date

2023-08-28, 1402/06/06

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating The effect of peppermint oil on nausea, vomiting and post-operative pain in patients undergoing Rhinoplasty surgery: A Randomized Controlled Trial

**Public title**

Investigating The effect of peppermint oil on nausea, vomiting and post-operative pain in patients

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Being at least 18 years old and at most 65 years old under elective rhinoplasty and septorhinoplasty surgery  
Not allergic to mint No smoking and drugs Patients should be in ASA class (I, II). Not breastfeeding

**Exclusion criteria:**

Failure to comply with the desired anesthesia protocol  
Receiving anti-nausea medication before or during anesthesia Reluctance to cooperate

**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: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

random allocationThe number of 64 eligible patients will be continuously selected and after obtaining written consent, they will be randomly divided into two intervention and control groups. Online software (<https://www.randomizer.org/>) will be used for random allocation of samples in two groups. In this method, the number of 64 closed envelopes with a number from 1 to 64 written inside each envelope will be placed in front of the patient and based on the number inside the envelope and the list of numbers obtained by the software, the patient will be placed in one of two groups.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Gilan University of Medical Sciences

**Street address**

Gilan-Masal-Sharek town-Azadegan 1-Plaque 25

**City**

rasht

**Province**

Guilan

**Postal code**

4381757399

**Approval date**

2023-04-19, 1402/01/30

**Ethics committee reference number**

IR.GUMS.REC.1402.033

**Health conditions studied****1****Description of health condition studied**

patients undergoing Rhinoplasty surgery

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Nausea

**Timepoint**

Recovery, ward, one hour after entering the ward

**Method of measurement**

Questionnaire of demographic information and to check vomiting through observation and evaluation of nausea based on nursing reports and patients' statements and also VAS scale for pain is used.

**2****Description**

Recovery, ward, one hour after entering the ward

**Timepoint**

Recovery, ward, one hour after entering the ward

**Method of measurement**

Questionnaire of demographic information and to check vomiting through observation and evaluation of nausea based on nursing reports and patients' statements and also VAS scale for pain is used.

## Secondary outcomes

### 1

#### Description

pain

#### Timepoint

Recovery, ward, one hour after entering the ward

#### Method of measurement

VAS scale for pain.

## Intervention groups

### 1

#### Description

Intervention group: Peppermint essential oil... patients in the case group are prescribed 20 oral drops (2% peppermint essence) made by Alice company half an hour before surgery

#### Category

Prevention

### 2

#### Description

Control group: Distilled water. The control group uses 20 drops of distilled water, which is similar in color to the original drug, so that the blinding process is carried out as much as possible.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amir Al Mo'menin Educational Remedial & Research Center

##### Full name of responsible person

Arman Parvizi

##### Street address

Behind the courthouse, 17 Shahrivar Ave,Rasht Town

##### City

Rasht

##### Province

Guilan

##### Postal code

4381757399

##### Phone

+98 13 4366 4045

##### Email

r\_pourmohammad@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Rasht University of Medical Sciences

#### Full name of responsible person

Mohammadreza Naghipour

#### Street address

In front of 17 Shahrivar Hospital,Namjo Ave,Shahid Siyadati Ave,Rash Town

#### City

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#### Phone

+98 13 3333 5821

#### Email

naghi@gums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

Guilan 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

Reza Pourmohammad

##### Position

MCS Surgical Technology

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

No.25,Azadegan1,Shahrak-e Vali Asr,Masal Town

##### City

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##### Postal code

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##### Phone

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##### Email

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Arman Parvisi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Email**

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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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**Position**

MSC surgical technology

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

En There is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available