

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 ± 2.85 and 2.43 ± 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammadreza Naghipour

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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

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Person responsible for scientific inquiries

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Latest degree

Specialist

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Person responsible for updating data

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Latest degree

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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