

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of peppermint essence inhalation on reduce the severity of nausea and vomiting in patients after open heart surgery

#### Protocol summary

##### Study aim

The object of study is determining the effect of peppermint essence inhalation on the reduction of nausea and vomiting in patients after open heart surgery

##### Design

This study is a randomized clinical trial, with double blind parallel group with sample size of 60 at least 30 per groups. The first phase of intervention will be made when patients have criteria of extubation. The second time of intervention will be made 4 hours after extubation by using of a nebulizer mask. The third intervention is after eight hours of extubation. The control group also received normal saline in the same three time .

##### Settings and conduct

This study will be carried out in the ward of the heart surgery of Kashan Shahid Beheshti Hospital. Peppermint essential to patients in the intervention group will be take after open heart surgery. Severity of nausea and vomiting of patients will be investigated after three times in the intervention and control groups. Blinding will be made for patients participating and analyzer.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Lack of any sensitivity to peppermint compounds, breathing problem, the lack of auditory and cognitive problems in order to answer questions of the questionnaire, elective surgery, Not taking nausea and vomiting drugs prior to surgery. Excluded criteria: Lack of cooperation to continue during the study, incidence of any sensitivity to peppermint, intolerance of peppermint essence smell, the patient's death, prescription of nausea and vomiting drugs

##### Intervention groups

Patients in the intervention group receive peppermint essence inhalation in 3 times, and patients in the control group in 3 times receive the normalsalin as placebo.

##### Main outcome variables

nausea and vomiting

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100124003146N5**

Registration date: **2019-02-10, 1397/11/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-02-10, 1397/11/21**

Update count: **0**

##### Registration date

2019-02-10, 1397/11/21

##### Registrant information

##### Name

Ismail Azizi-Fini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5554 0021

##### Email address

azizi-es@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-21, 1397/09/30

##### Expected recruitment end date

2019-03-21, 1398/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of peppermint essence inhalation on reduce the severity of nausea and vomiting in patients after open heart surgery

**Public title**

The effect of peppermint essence inhalation on reduce the severity of nausea and vomiting in patients after open heart surgery

**Purpose**

Treatment

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

All patients with open heart surgery above 18 years old  
Extubation after 12 hours of surgery  
Awareness after Extubation

**Exclusion criteria:**

All patients with open heart surgery above 18 years old  
Extubation after 12 hours of surgery  
Awareness after Extubation

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

At the beginning of each day, in order to prevent the revelation of the intervention and essence odor, it will be determined by the throwing of the coin and then randomly assigned to which of the intervention or control groups on the same day. Then patients who undergo surgery according to the routine are randomly assigned in the intervention or control groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study because the essential ingredient in the ward may be emitted, the cases of groups will be taken from each other in different days. Consequently, the samples in different groups will not be aware of the type of intervention. Also analyzer will not be aware on the type of intervention in groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

No

**Secondary Ids**

empty

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

Ethics committee of Kashan University of Medical Sciences

**Street address**

Ravand Ave., Parastar Blvd.

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715981151

**Approval date**

2018-12-08, 1397/09/17

**Ethics committee reference number**

Ir.Kaums.Nuhepm.Rec.1397.046

**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

**Timepoint**

Before of extubation, 4 hour after of extubation, 8 hour after of extubation

**Method of measurement**

Questionnaire

**2****Description**

Vomiting

**Timepoint**

Before of extubation, 4 hour after of extubation, 8 hour after of extubation

**Method of measurement**

Questionnaire

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Patients in the intervention group receive peppermint essence inhalation in 3 times

### Category

Treatment - Other

## 2

### Description

Patients in the control group in 3 times receive the normal saline as placebo

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Shahid Beheshti hospital of Kashan

#### Full name of responsible person

Mahla Maghami

#### Street address

Ravand Ave., Parastar Blvd.

#### City

Kashan

#### Province

Isfahan

#### Postal code

8715981151

#### Phone

+98 31 5554 0021

#### Email

mahlamaghmi@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Kashan University of Medical Sciences

#### Full name of responsible person

Hamid Reza Banafsheh

#### Street address

Ravand Ave., Parastar Blvd.

#### City

Kashan

#### Province

Isfahan

#### Postal code

8715981151

#### Phone

+98 31 5554 0021

#### Email

banafsheh\_h@kaums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor

### organization/entity?

Yes

### Title of funding source

Kashan 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

Kashan University of Medical Sciences

#### Full name of responsible person

Esmail Azizi

#### Position

Associate professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nursery

#### Street address

Ravand Ave., Parastar Blvd.

#### City

Kashan

#### Province

Isfahan

#### Postal code

8715981151

#### Phone

+98 31 5554 0022

#### Email

azizi\_es@kaums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kashan University of Medical Sciences

#### Full name of responsible person

Esmail Azizi

#### Position

Associate professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nursery

#### Street address

Ravand Ave., Parastar Blvd.

#### City

Kashan

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Isfahan

**Postal code**  
8715981151  
**Phone**  
+98 31 5554 0022  
**Email**  
azizi\_es@kaums.ac.ir

8715981151  
**Phone**  
+55 540021  
**Fax**  
**Email**  
mahlamaghmi@yahoo.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Mahla Maghami  
**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Ravand Ave., Parastar Blvd.  
**City**  
Kashan  
**Province**  
Isfahan  
**Postal code**

## 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

The release plan is not yet known

### 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