

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

**Comparison the effect of sucking ice containing peppermint extract with cardamom extract on prevention of nausea and vomiting after laparoscopic cholecystectomy in patients hospitalized to general surgery wards in Hamadan Besat hospital -2019. General surgery section of Besat Hospital in Hamedan at 2019 conducted a comparison study between sucking mint & cardamom flavored ice to avoid nausea & vomiting after laparoscopic cholecystectomy operation.**

### Protocol summary

#### Study aim

Comparison the effect of sucking ice containing peppermint extract with cardamom extract on prevention of nausea and vomiting after laparoscopic cholecystectomy in patients hospitalized to general surgery wards

#### Design

Randomized clinical trial with parallel groups, 90 patients.

#### Settings and conduct

The place of the study is the general surgery wards in Hamadan Besat hospital. In the ice group containing peppermint extract, 6 drops of peppermint extract 10%, mixed with 1 cc of water, we'll pour within round plastic containers, and we'll put it within the hospital's refrigerator. Finally, we will prepare 4 pieces of ice with this method, which every 15 minutes will put one of these ices under the tongue of the patient, and we will ask him until its complete solution, do not swallow it. These ices will be used for an hour (a total of 4 pieces of ice). Intervention group: In the cardamom group, will be used 4 pieces of ice containing 6 drops of 10% cardamom extract, which will be ready like as peppermint extract. Intervention group: In the placebo group will be used 4 pieces of ice, without any additive substance, which will be ready in dimensions of two previous groups.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: having nausea before the intervention; age over 18 years old; not sensitive to peppermint and cardamom extract. Exclusion criteria: discharge before

the end of the intervention

#### Intervention groups

Three groups, ice group containing peppermint extract, ice group containing cardamom extract, and placebo group

#### Main outcome variables

nausea and vomiting

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20170123032129N7**

Registration date: **2019-07-17, 1398/04/26**

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

Last update: **2019-07-17, 1398/04/26**

Update count: **0**

#### Registration date

2019-07-17, 1398/04/26

#### Registrant information

##### Name

Azim Azizi

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 0150

##### Email address

a.azizi@umsha.ac.ir

**Recruitment status**

Recruitment complete

**Funding source****Expected recruitment start date**

2019-07-11, 1398/04/20

**Expected recruitment end date**

2019-11-22, 1398/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison the effect of sucking ice containing peppermint extract with cardamom extract on prevention of nausea and vomiting after laparoscopic cholecystectomy in patients hospitalized to general surgery wards in Hamadan Besat hospital -2019. General surgery section of Besat Hospital in Hamedan at 2019 conducted a comparison study between sucking mint & cardamom flavored ice to avoid nausea & vomiting after laparoscopic cholecystectomy operation.

**Public title**

Comparison the effect of sucking ice containing peppermint extract with cardamom extract on prevention of nausea and vomiting

**Purpose**

Prevention

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

Age over 18 years old.To be more than 18 years old  
Having nausea before the intervention. vomiting before intervention. Not sensitive to peppermint and cardamom extract

**Exclusion criteria:**

Discharge before the end of the intervention.Release prior end of intervention process Vomiting without nausea before or during the intervention.Vomiting not coupled with nausea before or meantime of intervention.

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **105**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using blocking method (three-block method), three letters A, B, and C with different permutations will be placed in blocks, then 35 blocks will be randomly selected, then participants will be assigned to three groups based on selected triple blocks.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of Hamadan University of Medical Sciences

**Street address**

Shahid Fahmideh Street, Hamadan University of Medical Sciences, Hamadan

**City**

Hamadan

**Province**

Hamadan

**Postal code**

38698-65178

**Approval date**

2019-06-15, 1398/03/25

**Ethics committee reference number**

IR.UMSHA.REC.1398.233

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

Cholecystitis

**ICD-10 code**

K80.0

**ICD-10 code description**

Calculus of gallbladder with acute cholecystitis

**Primary outcomes****1****Description**

nausea

**Timepoint**

1 and 3 hours after intervention

**Method of measurement**

visual analogue scale to measure severity of nausea

**2****Description**

Vomiting

**Timepoint**

1 and 3 hours after intervention

## Method of measurement

Count of frequency of vomiting

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group (ice containing peppermint extract): 6 drops of peppermint extract 10%, mixed with 1 cc of water will be poured inside round plastic containers, and will be put inside the hospital's refrigerator. then 4 pieces of ice will be put every 15 minutes under the tongue of the patient. Patient will be asked not to swallow it until complete solution. These ices will be used for an hour (a total of 4 pieces of ice).

#### Category

Prevention

### 2

#### Description

Intervention group (cardamom group): 4 pieces of ice containing 6 drops of 10% cardamom extract, will be prepared and administered similar to peppermint extract.

#### Category

Prevention

### 3

#### Description

Intervention group: In the placebo group will be used 4 pieces of ice, without any additive substance, which will be ready similar to two previous groups.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat hospital

##### Full name of responsible person

Azim Azizi

##### Street address

Shahid Fahmideh Street, Hamadan University of Medical Sciences, Hamadan

##### City

Hamadan

##### Province

Hamadan

##### Postal code

38698-65178

##### Phone

+98 81 3838 0535

## Email

A.azizi@umsha.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Saeed Bashirian

##### Street address

Shahid Fahmideh Street, Hamadan University of Medical Sciences, Hamadan

##### City

Hamadan

##### Province

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##### Postal code

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##### Phone

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##### Email

s.bashirian@umsha.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

##### Full name of responsible person

Azim Azizi

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Azim Azizi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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Hamedan University of Medical Sciences

**Full name of responsible person**

Azim Azizi

**Position**

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**Latest degree**

Ph.D.

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**Email**

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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**

There is no more information.

**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