

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.

AgeFrom **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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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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**

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

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Person responsible for updating data**Contact****Name of organization / entity**

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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