Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effect of Peppermint Extract with Placebo on Reducing Postoperative Pain During Elective Cholecystectomy

Protocol summary

Study aim

The aim of this study was to determine the effect of mint extract on reducing the severity of postoperative pain in cholecystectomy

Design

This is a double-blind clinical trial carried out in Emdad hospital of Sabzevar City. This study conducted on a total of 107 patients (47 placebo and 60 drug patients), who were candidate for cholecystectomy. Drug and placebo (40 drops three times every 20 minutes) were administered to patients suffering from postoperative pain after the recovery or stimulation of the gag reflex and onset of pain. The effect of mint extract on pain intensity was evaluated using the visual analog scale

Settings and conduct

This is a double-blind clinical trial conducted in Emdad Hospital in Sabzevar city on 107 patients undergoing open cholecystectomy.

Participants/Inclusion and exclusion criteria

The personal satisfaction to participate in the study Not having any mental or other illnesses

Intervention groups

Intervention group: 60 people are in the intervention group. Mint extract (40 drops three times every 20 minutes) was administered to patients suffering from postoperative pain after the recovery or stimulation of the gag reflex and onset of pain. The effect of mint extract on pain intensity was evaluated using the visual analog scale. Control group: 60 people are in the control group. Placebo (40 drops three times every 20 minutes) was administered to patients suffering from postoperative pain after the recovery or stimulation of the gag reflux and onset of pain. The pain intensity is evaluated using visual pain scale.

Main outcome variables

The severity and duration of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170404033202N8**
Registration date: **2018-01-12, 1396/10/22**
Registration timing: **prospective**

Last update: **2018-01-12, 1396/10/22**
Update count: **0**

Registration date

2018-01-12, 1396/10/22

Registrant information

Name

Atefeh Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4422 9180

Email address

a.asadi.mm.1384@gmail.com

Recruitment status

Recruitment complete

Funding source

Investigation

Expected recruitment start date

2018-02-19, 1396/11/30

Expected recruitment end date

2018-05-21, 1397/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effect of Peppermint Extract with Placebo on Reducing Postoperative Pain During Elective Cholecystectomy

Public title
Effect of mint extract on pain relief after elective cholecystectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Have personal consent Weight between 40 and 120 kg Age between 75 and 25 years Elective surgery
Exclusion criteria:
Physical and mental illness Use opioid or alcohol History of surgery less than 3 years ago Receive fentanyl more than 2 micrograms per kilogram body weight before surgery or antiemetic as a precursor.
Age
From **25 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **107**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients, researcher and analysist are not aware of the contents of the capsules.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences
Street address
Central Office of the University of Medical Sciences - Asadabadi Street
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617684155
Approval date
2017-09-23, 1396/07/01
Ethics committee reference number
IR.Medsab.Rec.1395.146

Health conditions studied

1

Description of health condition studied
Pain after elective cholecystectomy
ICD-10 code
K90-93
ICD-10 code description
K91.5 Postcholecystectomy syndrome

Primary outcomes

1

Description
Severity of pain
Timepoint
1 hour after the onset of the medication
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 60 people are in the intervention group. Mint extract (40 drops three times every 20 minutes) was administered to patients suffering from postoperative pain after the recovery or stimulation of the gag reflex and onset of pain. The effect of mint extract on pain intensity was evaluated using the visual analog scale.
Category
Treatment - Drugs

2

Description
Control group: 60 people are in the control group. Placebo (40 drops three times every 20 minutes) was administered to patients suffering from postoperative pain after the recovery or stimulation of the gag reflux and onset of pain. The pain intensity is evaluated using visual pain scale.
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emdad Shahid Beheshti hospital in Sabzevar

Full name of responsible person
Mohammad Nematshahi

Street address
Emdad Shahid Beheshti hospital, Kooshk Street

City
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Razavi Khorasan

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9617684155

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9157638703mn@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Fereshteh GHorat

Street address
Pardiss University, Koosar Street, Touhid Blvd

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ghorat.f@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences

Full name of responsible person
Atefeh Asadi

Position
G.P.

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Department of Health, Talghani Street

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Mohammad Nematshahi

Position
Anesthesiologist

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Position
G.P.
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
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