

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of nicotine patch on reduction of nausea and vomiting and pain following bile duct surgery using laparoscopic method

Protocol summary

Summary

The study, which is triple-blind clinical trial to evaluate the effect of nicotine patch on the nausea and vomiting and pain after the surgery is performed. Patients between the ages of 18 and 65 and non-smokers will be included in the study. The population studied was all patients undergoing laparoscopic cholecystectomy. The sample size included 100 patients. Patients were randomly divided into two groups of 50 people will be treated with medication and placebo. One hour prior to the operation, the nicotine patch and placebo was installed for 24 hours and the pain and nausea and vomiting of the patients will be recorded at 1, 6, 12 and 24 hours. Patients' pain will be assessed with a visual analogue scale and to measure nausea and vomiting Checklist will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092336328N1**

Registration date: **2017-10-04, 1396/07/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-04, 1396/07/12

Registrant information

Name

Sajjad Dindar

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3372 0771

Email address

s.dindar@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research of Ardabil University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nicotine patch on reduction of nausea and vomiting and pain following bile duct surgery using laparoscopic method

Public title

The effect of nicotine patch on reducing nausea and vomiting and postoperative pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: aged 18 to 65 years of age ; Non-smoking patients ; Not having a history of heart disease and nervous disorders, diabetes and hypertension
Exclusion criteria: Patients with scores of pain above 8 on the basis of pain assessment criteria ; Receiving an additional pain reliever for pain control ; Patients requiring laparotomy ; Patients unable to maintain a nicotine patch for 24 hour

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ardabil University of Medical Sciences

Street addressArdabil - Kowsar Town - Central Office of Ardabil
University of Medical Sciences**City**

Ardabil

Postal code

06189-80991

Approval date

2017-08-06, 1396/05/15

Ethics committee reference number

Ir.Arums.rec.1396.82

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

nausea and vomiting

ICD-10 code

K91.0

ICD-10 code description

Vomiting following gastrointestinal surgery

2**Description of health condition studied**

Postoperative pain

ICD-10 code

R52.9

ICD-10 code description

Pain, unspecified

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

Pain

Timepoint

1st, 6th, 12th and 24th hours after surgery

Method of measurement

Visual Scale of Pain

2**Description**

nausea and vomiting

Timepoint

1st, 6th, 12th and 24th hours after surgery

Method of measurement

Nausea and vomiting evaluation checklist

Secondary outcomes

empty

Intervention groups**1****Description**In the intervention group labels containing 17.5 mg
nicotine for 24 hours, were made in England**Category**

Treatment - Drugs

2**Description**In the control group, the drug-free labels of Osveh
Company were used.**Category**

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital in Ardebil

Full name of responsible person

Ali Ali mohamadi

Street address

Ardebil , Ataee Street , Imam Khomeini Hospital

City

Ardabil

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Shahrah Habibzadeh

Street address

Ardabil, Daneshgah st. Ardabil Complex University,
Deputy Research and Technology

City

Ardabil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardabil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Mir salim Seyed sadeghi

Position

Assistant Professor

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

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Full name of responsible person

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Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Student

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty