

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 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 size

Target 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 address

Ardabil - Kowsar Town - Central Office of Ardabil
University of Medical Sciences

City

Ardabil

Postal code

۵۶۱۸۹-۸۵۹۹۱

Approval date

2017-08-06, 1396/05/15

Ethics committee reference number

lr.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

Street address

Sarein Station, Imam Khomeini Street, not reaching
Shariati Square, Fatemi Educational and Therapeutic
Center

City

Ardabil

Postal code

5614733775

Phone

+98 45 3323 2520

Fax

Email

fatemi@arums.ac.ir s.seyedsadegi@arums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Khatereh Isazade far

Position

Assistant Professor

Other areas of specialty/work

Street address

Ardebil, Janbazan Square, University Street End,
above University Square, Faculty of Medicine and
Paramedicine

City

Ardabil

Postal code

Phone

+98 45 3351 0052

Fax

Email

g.motavalli@arums..ac.irkh.isazadehfar@arums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Sajjad Dindar

Position

Student

Other areas of specialty/work

Street address

Ardebil, Janbazan Square, University Street End,
above University Square, Faculty of Medicine and
Paramedicine

City

Ardabil

Postal code

Phone

+98 45 3372 0771

Fax

Email

sajjad.dindar@yahoo.coms.dindar@arums.ac.ir

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