

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Effectiveness of trans-dermal fentanyl patch on postoperative pain of esophagus cancer with transhiatal method surgery

Protocol summary

Summary

Sixty patients with ASA class I and II, 20-80 years who will candidate for esophagus cancer with Transhiatal method surgery, randomly divided into two groups of 30: The F group = Trans-dermal Fentanyl patch and the M group = intravenous morphine An exclusion criterion is patients who have history of allergy to narcotics. The anesthetic method is the same in both groups. In Fentanyl group (F), a Trans-dermal Fentanyl patch 50µg/h will administer one hour prior to anesthesia induction on anterolateral skin of the thorax. In M group, after the operation, 4 mg of morphine will inject every 6 hours. After tracheotomy, the patients is transfer to ICU and their entrance time to ICU is consider as the time zero and they will monitor for 72 hours afterwards. Pain score of the patients will record throughout the next 72 hours after thoracotomy in 0, 2, 4, 6 and every 6 hours afterwards and a minute prior to morphine injection. The pain score evaluate by using visual analogue scale, (0-10 number). In case of need for adequate analgesia, with a VAS more than 4, 4 mg of intravenous morphine will inject in both groups. At the end of the study we compare the mean amount of morphine and VAS in the two groups. We will record Vital signs such as systolic, Diastolic blood pressure, heart rate, respiratory rate every 6 hours in the ICU. We will record demographic data such as age, sex, weight and duration of surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110107752N1**
Registration date: **2012-03-17, 1390/12/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-17, 1390/12/27

Registrant information

Name

Parviz Amri Maleh

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1223 8296

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pamrimaleh@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor of research Babol university of Medical Sciences

Expected recruitment start date

2012-02-07, 1390/11/18

Expected recruitment end date

2013-02-06, 1391/11/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of trans-dermal fentanyl patch on postoperative pain of esophagus cancer with transhiatal method surgery

Public title

Effectiveness of trans- dermal fentanyl patch on postoperative pain of esophagus cancer surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Elective esophagus cancer surgery; patients with ASA class I and II; transhiatal method surgery; general Anesthesia; The age range 20 to 80 years old. Exclusion criteria :History of allergies to opioid; any contraindication for trans-dermal Fentanyl patch and morphine; addiction to alcohol or narcotics; dementia ; psychological disorders ; skin diseases preventing the administration of TFP; pregnant ; breast-feeding mothers.

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-chancellor of research of Babol University of Medical Sciences

Street address

Gangafrooz St, Babol University of Medical Sciences

City

Babol

Postal code

4717641367

Approval date

2012-02-07, 1390/11/18

Ethics committee reference number

5720/30/پ/ز

Health conditions studied

1

Description of health condition studied

oesophagus cancer

ICD-10 code

C15.9

ICD-10 code description

Oesophagus, unspecified

Primary outcomes

1

Description

postoperative pain

Timepoint

72 h after intervention

Method of measurement

visual analog scale

Secondary outcomes

1

Description

respiration

Timepoint

72 h

Method of measurement

Resoiratory rate per minute

2

Description

systolic blood pressure

Timepoint

72 h postoperation

Method of measurement

mm/Hg

3

Description

diastolic blood pressure

Timepoint

72 h postoperation

Method of measurement

mm/Hg

4

Description

mean amount of morphine

Timepoint

72 h postoperation

Method of measurement

miligram

Intervention groups

1

Description

In intervention group: A patch of 50µg/h Fentanyl was administered on antrolateral of chest wall one hour prior to anesthesia .

Category

Treatment - Drugs

2

Description

In control group:After operation 4 mg of IV morphinewas injected every 6 hours .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rohani Hospital

Full name of responsible person

Amrimaleh. Parviz

Street address

Gangafrooz Str, Ayatollah Rohani Hospital

City

Babol

2

Recruitment center

Name of recruitment center

Shahid Behshti Hospital

Full name of responsible person

Nikbakhsh, MD.

Street address

Ganafrooz St, Shahid Behshti Hospital

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor of research, Babol University of Medical Sciences

Full name of responsible person

Mostafazadeh, Amrolah

Street address

Gangafrooz St, Babol University of Medical sciences

City

Babol

Grant name

Grant code / Reference number

714578

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

Yes

Title of funding source

Vice-chancellor of research, Babol 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

Babol University of Medical Sciences

Full name of responsible person

Amrimaleh,Parviz

Position

Anesthesiologist,FCCM

Other areas of specialty/work

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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