

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Trans-dermal Fentanyl patch compared to intravenous morphine, efficacy on post thoracotomy pain

Protocol summary

Summary

In randomized clinical trial study, fifty patients with ASA class I and II who were candidates for elective thoracic surgery ,randomly divided into two equal groups . All thoracotomy were performed by the same surgeon.Exclusion criteria are history of allergies to opioid, addiction to alcohol or narcotics. In intervention group, One hour prior to general anesthesia induction, a trans-dermal fentayl patch (Duragesic 50 µg/h) was placed on anterolateral skin of the thorax. Anesthetic method was the same in all of them. After thoracotomy, the patients were transferred to ICU and their entrance time to ICU was considered as the time zero and they were monitored for 72 hours. Vital signs of the patients including heart rate, Systolic and Diastolic blood pressure and respiratory rate in ICU were measured and recorded every six hours. In group M, we used 4 mg of IV morphine sulfate every 6 hours after thoracotomy.Pain score of the patients was evaluated with facial expression type of Visual Analogue Scale (VAS)and recorded throughout the next 72 hours after thoracotomy in 0, 2, 4, 6 and every 6 hours afterwards and a minute prior to IV morphine. In each groups in case of need and expressing pain by the patient with a VAS more than II, 4 mg of intravenous morphine was injected as supplementary analgesia. At the end of the study VAS and the amount of Morphine necessary for analgesia in the two groups was compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203067752N2**

Registration date: **2012-03-17, 1390/12/27**

Registration timing: **retrospective**

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

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor of research of Babol University of Medical Science

Expected recruitment start date

2009-05-25, 1388/03/04

Expected recruitment end date

2010-05-25, 1389/03/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Trans-dermal Fentanyl patch compared to intravenous morphine, efficacy on post thoracotomy pain

Public title

Trans-dermal Fentanyl patch compared to intravenous morphine, efficacy on post thoracotomy pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with ASA class I and II; who were candidates for elective thoracic surgery. Exclusion criteria: History of allergies or hypersensitivity to opioid; addiction to alcohol or narcotics; dementia; psychological disorders; skin diseases that preventing the absorption of transdermal fentanyl patch; pregnant or breast-feeding mothers; the patients undergoing intra pleural or intercostals blockage.

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: **50**

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

Approval date

2009-05-25, 1388/03/04

Ethics committee reference number

303858/ز.پ

Health conditions studied

1

Description of health condition studied

Postoperative thoracic surgery pain management

ICD-10 code

J95.9

ICD-10 code description

Postprocedural respiratory disorder, unspecified

Primary outcomes

1

Description

Postoperative pain

Timepoint

72 hours postoperative

Method of measurement

Visual Analog Scale

2

Description

The amount of Morphine

Timepoint

72 hours postoperative

Method of measurement

milligram

Secondary outcomes

1

Description

Systolic Blood Pressure

Timepoint

72 h postoperative

Method of measurement

mm/Hg

2

Description

Diastolic Blood Pressure

Timepoint

72 h postoperative

Method of measurement

mm/Hg

3

Description

Respiratory depression

Timepoint

72 h postoperative

Method of measurement

Respiratory rate for min.

4

Description

Heart Rate

Timepoint

72 h postoperative

Method of measurement

Heart Rate for 1 min.

Intervention groups

1

Description

In intervention group : One hour prior to general anesthesia induction, a TFP (Duragesic 50 µg/h) was placed on anterolateral skin of the thorax .

Category

Treatment - Drugs

2

Description

In control group: 4 mg of IV morphine sulfate was every 6 hours after thoracotomy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaid Beheshti Hospital

Full name of responsible person

Nikbakhsh, Novin

Street address

Gangafrooz St, Shahid Behshti Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor of research of Babol University of Medical Sciences

Full name of responsible person

Mostafazadeh, Amrolah

Street address

Gangafrooz St, Babol University of Medical sciences

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor of research of 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