Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Country
Iran (Islamic Republic of)
Phone
+98 11 1223 8296
Email address
pamrimaleh@mubabol.ac.ir

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 forelective 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 oftransdermal fentanil 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/ژ/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 paine
Timepoint
72 hours postoperative
Method of measurement
Visual Analog Scale

2

Description
The amount of Morphine
Timepoint
72 hours postoperative
Method of measurement
miligram

Secondary outcomes

1

Description
Systolic Blood Pressure
Timepoint
72 h postoperative
Method of measurement
mm/Hg

2

Description
Diaystolic Blood Pressure
Timepoint
72 h postoperative
Method of measurement
mm/Hg

3

Description
lRespiratory 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
Ganafrooz St, Shahid Behshti Hospital
City
Babol

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
City
Babol
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
Anestesiologist, FCCM
Other areas of specialty/work
Street address
Gangafrooz St, Rohani teaching Hospital
City
Babol
Postal code
4717641367
Phone
+98 11 1223 8296
Fax
+98 22 38296
Email
pamrimaleh@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Amrimaleh, Parviz
Position
Anestesiologist, FCCM
Other areas of specialty/work
Street address
Gangafrooz St, Babol University of Medical Sciences
City
Babol
Postal code
47176
Phone
+98 11 1219 9591
Fax
+98 22 38296
Email
pamrimaleh@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Amrimaleh, Parviz
Position

Anestesiologist,FCCM
Other areas of specialty/work
Street address
Gangafrooz St, Babol University of Medical Sciences
City
Babol
Postal code
4717641367
Phone
+98 11 1223 8296
Fax
+98 981112238296
Email
pamrimaleh@yahoo.com
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