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Randomized clinical trial of transdermal fentanyl patch as part of fast-track thoracic surgery postoperative pain management protocol

Submission date
25/09/2018

Recruitment status
No longer recruiting

Registration date
29/10/2018

Overall study status
Completed

Last Edited
25/01/2021

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Fast-track surgery represents a new approach optimizing surgical care including patient management before, during and after surgery. Even nowadays, in the era of minimally invasive interventions, thoracic (chest) surgery often causes severe pain afterward, which can significantly affect recovery, the patient's return to daily activities and the final outcome. There is still not enough evidence of the effectiveness of the transdermal fentanyl patch (TFP) in patients undergoing minimally-invasive thoracic surgery. As pain control remains an important challenge to the surgeon and to health care systems, clinical studies are required to find the best method of pain relief after surgery. The aim of this study is to find out whether using TFP within the concept of fast-track surgery helps with patient recovery, is safe and improves pain control during hospital stay and after discharge.

Who can participate?
Patients aged 18 and over undergoing lung resection by video-assisted thoracoscopic surgery (VATS)

What does study involve?
One day before surgery patients are randomly allocated receive a patch either with fentanyl or without it (placebo) applied on the shoulder skin and covered with neutral skin dressing. Patients are asked to evaluate pain intensity on a scale from 0 to 10 before surgery, directly after the surgery, 3-5 hours later, on the first and second day after and on the day of discharge. Patients are also called after discharge to ask about pain severity on the next day after discharge and 30 days after discharge. Patients are also asked about side effects (nausea, vomiting, and others). Apart from the study drug patients also receive standard combined pain relief, so that placebo group patients (without fentanyl patch) receive adequate pain relief in the same manner as the treatment group patients.

What are the possible benefits and risks of participating?
The results of this study may help health providers to decrease pain in patients undergoing this type of surgery, as well as to ensure faster and easier recovery. As with as any other drug, fentanyl can cause some side effects as nausea, vomiting, confusion, respiratory depression (slow breathing) and allergic reactions.

Where is the study run from?
Pauls Stradins Clinical University Hospital (Latvia)

When is the study starting and how long is it expected to run for?
September 2018 to February 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Anastasija Bistrova

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomized clinical trial of transdermal fentanyl patch as part of fast-track thoracic surgery postoperative pain management protocol

Study objectives

Use of transdermal fentanyl patches facilitates recovery after video-assisted thoracoscopic surgery (VATS) enabling more stable and efficient postoperative pain control during hospital stay and after discharge.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pauls Stradins Clinical University Hospital ethics committee, 23/04/2018, Nr. 230418-26L

Study design
Randomized single-blinded placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Postoperative pain intensity in patients after video-assisted thoracoscopic surgery

Interventions
Simple randomization based on a single sequence of random assignments, allocation ratio 1:1. After randomization patients will be allocated to two groups: transdermal fentanyl patch group (TFP) and placebo group (P). The TFP group will receive a long-acting (72 hours) low dose (25 µg /hr) transdermal fentanyl patch. Placebo group patients will receive a similar looking patch without any active substance applied at the same time as for the TFP group patients. Patches will be applied on the shoulder skin and covered with neutral skin dressing in both group. All patches will be replaced every 72 hours and on the day of discharge unless there are side effects. At the end of surgery both groups will receive an intercostal nerve block with 20 ml of 0.25 % bupivacaine solution. Postoperatively both groups receive standard postoperative care and multimodal analgesia with acetaminophen 1 g three times a day and lornoxicam 8 mg two times a day for baseline pain control. Postoperative combined analgesia also includes trimeperidine 20 mg when necessary (0-4 times a day) for breakthrough pain. All patients receive 20 ml of lactulose oral solution per day as prophylaxis of opioid-related constipation. After discharge patients will be prescribed oral codeine 60 mg in combination with acetaminophen 1 g three to four times a day or when necessary.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Fentanyl

Primary outcome measure
Intensity of postoperative pain assessed by visual analogue pain scale (VAS) and scored on a numeric rating scale from 0 (no pain) to 10 (the worst imaginable pain). Assessed before surgery, directly after the surgery, 3-5 hours later, on the first and second postoperative day and on the day of discharge. After discharge patients will be followed-up twice by telephone to assess pain severity on the next day after discharge and 30 days after discharge.

Secondary outcome measures
1. Presence of nausea or vomiting, signs of respiratory depression and confusion, assessed by asking before surgery, directly after the surgery, 3-5 hours later, on the first and second postoperative day, on the day of discharge, as well as on the next day after discharge and 30 days after discharge
2. Requirement of rescue medication (trimeperidine) for breakthrough pain, length of postoperative hospital stay and duration of chest drainage collected from patients' history on the day of discharge

Overall study start date
01/09/2018

Completion date
01/04/2020

Eligibility

Key inclusion criteria
1. Age ≥ 18 years
2. Lung resection (lobectomy, segmentectomy or wedge resection) performed by two-port VATS
3. WHO performance status range between 0 and 2
4. BMI range between 19 and 29

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
>50

Key exclusion criteria
1. Prior use of nonsteroidal anti-inflammatory drugs or opioid analgesics
2. Particular drug intolerance (fentanyl, bupivacaine, acetaminophen, trimeperidine, lornoxicam)
3. Postoperative hospital stay > 8 days
4. VATS conversion to thoracotomy
5. Mental disorders
6. Narcotic addiction
7. Chronic pain syndrome
8. Inability to assess severity of pain using Visual Analogue Scale (VAS)

Date of first enrolment
08/10/2018

Date of final enrolment
14/01/2019

Locations

Countries of recruitment
Latvia

Study participating centre
Pauls Stradins Clinical University Hospital
Pilsonu 13
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Sponsor information

Organisation
Pauls Stradins Clinical University Hospital Research Institute

Sponsor details
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Sponsor type
Research organisation

ROR
https://ror.org/00h1aq868

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 25/01/2021:
The trialists are planning to write an original article based on this trial and publish it in peer-reviewed journals. No participant data will be published, only statistical information regarding results of the trial. Additional documents (study protocol, statistical analysis plan) will be included in the subsequent results publication.

Previous publication and dissemination plan:
The trialists are planning to write an original article based on this trial and publish it in European Journal of Cardiothoracic Surgery in April 2019. No participant data will be published, only statistical information regarding results of the trial. Additional documents (study protocol, statistical analysis plan) will be included in the subsequent results publication.

Intention to publish date
01/03/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be included in the subsequent results publication.

IPD sharing plan summary
Other