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Ultrasound guided continous serratus anterior plane block: dexmedetomidine as an adjunctive analgesic with levobupivacine for post thoracotomy pain

Submission date
12/04/2017

Recruitment status
No longer recruiting

Registration date
19/04/2017

Overall study status
Completed

Last Edited
24/05/2019

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Thoracic surgery includes operations on all parts of the chest including the chest wall, the contents of the chest and the lungs, except for heart surgery. A thoracotomy is a surgical incision (cut) into the chest wall to open the chest cavity. Post-thoracotomy pain is felt in the back and chest region after a thoracotomy. The aim of this study is to find out whether dexmedetomidine plus local anesthetic Levobupivacaine could extend pain relief time compared with Levobupivacaine alone at the end of thoracic surgery.

Who can participate?
Patients aged 20-60 undergoing elective thoracic surgery

What does the study involve?
Participants are randomly allocated to one of two groups. One group receive levobupivacaine and the other group receive levobupivacaine plus dexmedetomidine. Participants' pain, opioid (pain relief) consumption and adverse effects are monitored.

What are the possible benefits and risks of participating?
The results of this study will help to confirm the best method of pain relief and the patient may benefit from pain relief. No risks are expected.

Where is the study run from?
National Cancer Institute, Cairo University (Egypt)

When is the study starting and how long is it expected to run for?
March to September 2017

Who is funding the study?
National Cancer Institute, Cairo University (Egypt)

Who is the main contact?
Dr Ahmed Bakir
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
201617011.2p

Study information

Scientific Title
Ultrasound guided continous serratus anterior plane block :dexmedetomidine as an adjunctive analgesic with levobupivacine for post thoracotomy pain: a prospective randomized controlled study

Study objectives
Dexmedetomidine plus local anesthetic levobupivacaine could extend pain relief time compared only with levobupivacaine when ultrasound guided serratus anterior block is performed at the end of thoracic surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of National Cancer Institute, Cairo University, 04/04/2017, ref: 201617011.2b

Study design
Interventional prospective randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Post-thoracotomy pain

Interventions
Patients will be randomized by double-blind simple randomization to two groups.
1. 25 patients will receive a bolus of 30 ml of 0.25% levobupivacaine followed by an infusion of 5 ml/hour of 0.125% levobupivacaine.
2. 25 patients will receive a bolus of 30 ml of 0.25% levobupivacaine plus 1 ug/kg dexmedetomidine followed by an infusion of 0.125% levobupivacaine plus 0.2 ug/kg/hour dexmedetomidine at a rate of 5 ml/hour.
All patients receive the study medications through ultrasound-guided serratus anterior catheter.

Patients will be monitored for:
1. Arterial blood pressure, heart rate and oxygen saturation every 10 min for the initial one hour of the blockade; subsequently every half an hour for the next 2 hours and then 2 hourly for the next 12 hours. As soon as the patient is alert enough VAS pain score will be recorded every 2 hours
2. Total morphine consumption during first 24 hours postoperatively
3. Sign of morphine side effects such as nausea, vomiting, dizziness, an unusual pleasant feeling, sweating, headache, anxiety and constipation

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Levobupivacaine, dexmedetomidine

Primary outcome measure
Postoperative pain at rest and coughing, measured by VAS pain score (10 mm vertical scale from 0-10 where zero means no pain and 10 is the worst pain) every 2h in the first 24h postoperative

Secondary outcome measures
1. Postoperative opioid consumption, recorded by staff during first 24 hours postoperative
2. Adverse effects including nausea, vomiting, hypotension and cardiac arrhythmias, recorded by staff in the first 24h postoperative

Overall study start date
10/03/2017

Completion date
10/09/2017

Eligibility

Key inclusion criteria
1. Age from 20-60
2. ASA 2 or 3
3. Undergoing elective thoracic surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
25 patients in each group

Total final enrolment
50

Key exclusion criteria
1. Refusal of the patient
2. Coagulopathy
3. Severe cardiac or renal impairment or hepatic disease
4. Known allergy to the study drugs

Date of first enrolment
10/04/2017

Date of final enrolment
10/08/2017

Locations

Countries of recruitment
Egypt

Study participating centre
National Cancer Institute, Cairo University
Egypt
-

Sponsor information

Organisation
National Cancer Institute, Cairo University

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Sponsor type
University/education

ROR
https://ror.org/03q21mh05

Funder(s)

Funder type
University/education

Funder Name
National Cancer Institute, Cairo University

Alternative Name(s)
NCI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Egypt

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal

Intention to publish date
10/09/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ahmed Bakir (ahmed_bakir77@yahoo.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/04/2019	24/05/2019	Yes	No