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Paravertebral nerve blocks for analgesia after cardiac surgery

Submission date
10/07/2015

Recruitment status
No longer recruiting

Registration date
26/07/2015

Overall study status
Completed

Last Edited
09/06/2017

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
The aim of this study is to find out whether injecting a local anaesthetic into the back to block the nerves to the chest (a paravertebral injection) reduces pain after cardiac surgery. This is a technique of pain control the trialistshave been using recently and it sounds sensible, but it's hard to be sure that it really works because there are such big differences in the amount of pain people experience after cardiac surgery. What's more, just getting local anaesthetics into the blood stream reduces pain after other surgical operations, so it may be that paravertebral injections are working simply because the drug is being absorbed into the blood. This study is designed to clarify the situation.

Who can participate?
Patients undergoing coronary artery bypass grafting.

What does the study involve?
Patients are randomly allocated into one of two groups. Those in group 1 are given bilateral paravertebral blocks during surgery. Those in group 2 are given a dummy, or 'sham', injection under the skin. After surgery, patients are able to self-administer pain relief (morphine) as they need it, to see whether the patients with true paravertebral injections want less morphine than those with the sham injections.

What are the possible benefits and risks of participating?
It is hoped that all patients taking part get additional benefit from the local anaesthetic infusion. The catheters are placed under the same rigorous aseptic conditions as the rest of their surgery so no infections are expected.

Where is the study run from?
Hammersmith Hospital (UK)

When is study starting and how long is it expected to run for?
October 2014 to September 2016

Who is funding the study?
Imperial College Healthcare NHS Trust (UK)

Who is the main contact?
Dr Geoff Lockwood
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13HH1841

Study information

Scientific Title
A double blind, randomised controlled trial to assess the efficacy of bilateral paravertebral blockade for analgesia after cardiac surgery

Study objectives
Do paravertebral blocks provide useful analgesia by blocking specific nerves or are we simply seeing the systemic effects of the local anaesthetics as they are absorbed into the circulation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
London (Dulwich), 08/08/2014, ref: 14/LO/0864

Study design
Single centre interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Postoperative pain

Interventions
Bilateral paravertebral blockade or sham infusion of lidocaine

Intervention Type
Procedure/Surgery

Primary outcome measure
Morphine consumption using a PCA device

Secondary outcome measures
1. Pain (measured using ordinal scale) and respiratory function (PEFR) for first 7 days
2. Quality of life, measured using the EuroQol EQ-5D questionnaire at 3 months

Overall study start date
06/09/2013

Completion date
14/09/2016

Eligibility

Key inclusion criteria
1. Age 40-70 years
2. Undergoing elective and urgent first time coronary bypass surgery

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
50

Key exclusion criteria
1. Critical preoperative state
2. Single graft surgery (no leg incision)
3. Minimally invasive surgery (no sternotomy)
4. Significant renal disease (baseline creatinine >150 micromolar: morphine contraindicated)
5. Patients exceeding 110kg (4% of our operative population practical difficulties of positioning unconscious patients to place the block)
6. Pregnancy
7. Patients with chronic pain taking regular analgesic medication
8. Patients with a significant abnormality of coagulation
9. Participation in another interventional study
10. Patients unable to give informed consent
11. Hypersensitivity to lidocaine

Date of first enrolment
26/10/2014

Date of final enrolment
07/09/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hammersmith Hospital
Ducane Road
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Imperial College Healthcare

Sponsor details
Joint Research Compliance Office
Charing Cross Hospital
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Sponsor type
Hospital/treatment centre

Website
www.ic.ac.uk/clinicalresearchgovernanceoffice

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Imperial College Healthcare NHS Trust

Alternative Name(s)
Imperial NHS, imperialnhs, Imperial College Healthcare NHS Trust | London

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Peer-reviewed journal

Intention to publish date
30/03/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2017		Yes	No
HRA research summary			26/07/2023	No	No