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A comparison of co-codamol and modified-release morphine sulphate for step-down analgesia in patients following thoracotomy

Submission date 28/09/2007	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/09/2007	**Overall study status** Stopped	
Last Edited 28/08/2008	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0201184743

Study information

Scientific Title

Study objectives
1. The purpose of this study is to find out whether co-codamol or modified-release morphine provide better post-operative pain control following thoracotomy.
2. The secondary objective is to compare the incidence of complications and compare the compliance of the two analgesia regimens. Common complications include nausea, vomiting, pruritis (itchiness), sedation, lightheadedness, mobility and constipation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Pain

Interventions
Patients undergoing thoracotomy for the first time and not taking regular analgesia for another condition can be considered for this study.

Analgesia in the immediate post-operative period will be decided by consensus of surgeon, anaesthetist and the patient. They include epidural analgesia, PVB (paravertebral continuous analgesia) catheter and intravenous morphine either by continuous infusions or PCA. Every effort is made to ensure satisfactory pain relief.

Oral analgesia is commenced at least four hours before the paravertebral, epidural or IV morphine is stopped.

Patients will be randomised, by opening an envelope, into one of two groups to determine which of the two regimens they will receive:
Group 1: Co-codamol 30/500 2 tablets QDS PO. And unless contraindicated*: Diclofenac 75mg SR BD PO. For breakthrough pain: Tramadol 50–100mg QDS/PRN PO
Group 2: Paracetamol 1g QDS PO, MST Continus 20mg BD PO. And unless contraindicated*: Diclofenac 75mg SR bd PO. For breakthrough pain: Oramorph 10mg 1hrly/PRN PO

The MST dose should be adjusted on the second day to incorporate the 24 hour oramorph requirement.
* The contraindications for NSAIDs are gastroduodenal disease, renal impairment or a poor urine output. When used, patients should also receive omeprazole 20mg OD for gastric protection.

Added 28 August 2008: trial stopped due to poor recruitment.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
co-codamol and modified-release morphine sulphate

Primary outcome measure
1. Adequacy of pain control as measured by the visual analogue scale (0=no pain, 10=excruciating)
2. How frequently breakthrough analgesia is used overall satisfaction of pain control

Secondary outcome measures
Complications: nausea/vomiting, sedation, constipation, pruritis, mobility and compliance

Overall study start date
21/06/2006

Completion date
01/04/2008

Reason abandoned (if study stopped)
Poor recruitment

Eligibility

Key inclusion criteria
1. Patients >18 years
2. First-time thoracotomy patient
3. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
60 patients

Key exclusion criteria
1. Patients <18 years
2. Pregnancy
3. Breast-feeding
4. Not able to give informed consent
5. Already taking analgesia at time of admission

Date of first enrolment
21/06/2006

Date of final enrolment
01/04/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Brompton & Harefield NHS Trust
London
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

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Funder(s)

Funder type
Government

Funder Name
Royal Brompton and Harefield NHS Trust (UK), No External Funding, NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration