

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
Registration date 28/09/2007	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 28/08/2008	Condition category Signs and Symptoms	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Peter Goldstraw

Contact details

Royal Brompton & Harefield NHS Trust
Sydney Street
London
United Kingdom
SW3 6NP
+44 (0)20 7352 8121
P.Goldstraw@rbh.nthames.nhs.uk

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Royal Brompton & Harefield NHS Trust

London

United Kingdom

SW3 6NP

Sponsor information

Organisation

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration