

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

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/08/2008	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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

United Kingdom

SW3 6NP

**Sponsor information****Organisation**

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

**Sponsor details**

The Department of Health, Richmond House, 79 Whitehall  
London  
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**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

## **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