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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
28/09/2007	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/09/2007	Stopped	☐ Results
Last Edited	Condition category	Individual participant data
28/08/2008	5 5	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Contact information

### Type(s)

Scientific

#### Contact name

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### Contact details

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# 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

### Study design

Randomised controlled trial

### Primary study design

Interventional

### 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