

# A prospective, randomised, double-blind, placebo-controlled trial to assess the respiratory effects of oxycodone versus morphine in anaesthetised patients

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<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/10/2011	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## 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

N0205190802

# Study information

## Scientific Title

## Study objectives

To investigate to what extent modest and pre-defined degrees of respiratory depression may be produced by oxycodone and compare this to patients who receive intravenous morphine or placebo under identical conditions using a previously validated model.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Prospective randomised double-blind placebo-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

Surgery: Anaesthesia

## Interventions

A prospective randomised double-blind placebo-controlled trial.

Oxycodone 0.05mg/kg IV (12 patients), oxycodone 0.1mg/kg IV (12 patients), Oxycodone 0.2mg/kg IV (12 patients), morphine 0.1mg/kg IV (12 patients), or placebo - normal saline (6 patients)

## Intervention Type

Drug

## Phase

Not Specified

**Drug/device/biological/vaccine name(s)**

oxycodone versus morphine

**Primary outcome measure**

The extent to which oxycodone produces respiratory depression and compare this to morphine and placebo.

The primary endpoint is time to respiratory depression, defined as respiratory rate decreased by  $\geq 33\%$  and or end-tidal  $\text{CO}_2$  increased by  $\geq 1.5\text{kPa}$ .

**Secondary outcome measures**

To evaluate the extent of reversibility of any such respiratory depression by the administration of naloxone.

The principle secondary endpoint is the amount of naloxone required to reverse respiratory depression effects.

**Overall study start date**

13/12/2006

**Completion date**

12/12/2007

**Eligibility****Key inclusion criteria**

1. Patients aged 18-55 years
2. Patients who are ASA 1-2
3. Patients must be inpatients
4. Patients who are due to undergo surgery of greater than 30 minutes duration under GA
5. Patient has given written informed consent
6. Patient weighs between 45 and 100kg, and/or BMI  $\geq 30$

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

55 Years

**Sex**

Not Specified

**Target number of participants**

60

**Key exclusion criteria**

1. Patients who are allergic to oxycodone, naloxone or morphine
2. Patients with a history of substance abuse
3. Patients with a history of anaesthetic complications
4. Patients who have been on long-term opioid therapy, or have taken strong opioids within the last two weeks
5. Patients who are considered unsuitable by the responsible anaesthetist - for whom the required lengthening of the anaesthesia time is deemed to constitute an unacceptable increased risk
6. Patients who are involved in existing research
7. Patients who have any condition predisposing to respiratory depression

**Date of first enrolment**

13/12/2006

**Date of final enrolment**

12/12/2007

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

Anaesthetics Laboratory

London

United Kingdom

EC1A 7BE

**Sponsor information****Organisation**

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

**Sponsor details**

The Department of Health, Richmond House, 79 Whitehall

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**Sponsor type**

Government

**Website**

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

## Funder(s)

**Funder type**

Government

**Funder Name**

Barts and The London NHS Trust

**Funder Name**

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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/10/2010		Yes	No