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

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
18/10/2011

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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 ≥33% and or end-tidal CO^2 increased by ≥1.5kPa.

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 ≥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
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

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?
Results article	results	01/10/2010		Yes	No