ISRCTN91017061 https://doi.org/10.1186/ISRCTN91017061

Low-dose buprenorphine to prevent remifentanil-induced hyperalgesia after major lung resection: a prospective, randomised, controlled, double-blinded study

Submission date
09/03/2008

Recruitment status
No longer recruiting

Registration date
11/12/2008

Overall study status
Completed

Last Edited
11/12/2008

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
N/A

Study information

Scientific Title

Study objectives
Remifentanil is now considered one of the favourite agents for fast-track surgery. Despite its advantages, a remifentanil-based general anaesthesia seems to increase post-operative hyperalgesia, mainly during long or painful surgical procedures.

Treating acute post-operative remifentanil-induced hyperalgesia could have several benefits:
1. It could decrease post-operative stress reducing morbidity after surgery, improving patients outcomes and clinical expense
2. It could decrease analgesic related side effects and improve post-operative pulmonary function
3. It could reduce chronic pain outcomes after surgery

Recent evidences, both experimental and clinical, showed the role of N-methyl D-aspartate (NMDA)-receptor antagonists to prevent remifentanil-induced hyperalgesia. Among all the NMDA-antagonists commercially available, buprenorphine has unique and attractive features.

Hypothesis:
Does a low-dose continuous intra- and post-operative infusion of buprenorphine prevent remifentanil-induced hyperalgesia after open thoracic surgery, reducing post-operative morphine consumption and the extension of the primary hyperalgesic area around the incision site?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre, prospective, randomised, controlled, double-blinded study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Post-operative remifentanil-induced hyperalgesia

Interventions
All patients will receive remifentanil based general anaesthesia (target-controlled infusion [TCI] system), supplemented with oxygen and desflurane. Patients will then be randomised to:
1. Buprenorphine group: intra- and post-operative infusion of 25 µg/h of buprenorphine for 24 hours
2. Morphine group: intra- and post-operative infusion of 834 µg/h of morphine for 24 hours

Follow-up will occur until 30 days after hospital discharge.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Remifentanil-based general anaesthesia, oxygen, desflurane, buprenorphine, morphine

Primary outcome measure
Post-operative morphine consumption (PCA).

Secondary outcome measures
1. Morphine titration at the end of the surgery
2. Visual Analogue Scale (VAS) at rest and during coughing at 24 and 48 hours
3. Hyperalgesic area at 24 and 48 hours (Quantitative Sensory Testing)
4. Length of post-operative hospitalisation
5. Incidence of post-thoracotomy pain after one month from surgery

Overall study start date
01/04/2008

Completion date
01/10/2008

Eligibility

Key inclusion criteria
1. Adult patients (American Society of Anaesthesiologists [ASA] grade I - III) undergoing major lung resections
2. Aged greater than 18 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Extremely high or low weight (less than 40 kg and greater than 100 kg)
2. Known abuse of opioid drugs
3. Patients unable to manage a patient-controlled analgesia (PCA) device

Date of first enrolment
01/04/2008

Date of final enrolment
01/10/2008

Locations

Countries of recruitment
Italy

Study participating centre
Department of Anaesthesia and Critical Care Medicine
Rome
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Sponsor information

Organisation
La Sapienza University of Rome (Italy)

Sponsor details
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Sponsor type
University/education

Website
http://www.uniroma1.it/

ROR
https://ror.org/02be6w209

Funder(s)

Funder type
University/education

Funder Name
La Sapienza University of Rome (Italy) - 2nd Faculty of Medicine, Sant' Andrea Hospital, Department of Anaesthesia and Critical Care Medicine

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