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 | Prospectively registered Protocol |
|-------------------------------------|--|--|
| Registration date 11/12/2008 | Overall study status Completed | Statistical analysis plan Results |
| Last Edited 11/12/2008 | Condition category Skin and Connective Tissue Diseases | Individual participant data Record updated in last year |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Prof Roberto Arcioni

Contact details

Department of Anaesthesia and Critical Care Medicine 2nd Faculty of Medicine La Sapienza University of Rome Sant' Andrea Hospital Rome Italy 00189 roberto.arcioni@uniroma1.it

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 Italy 00189

Sponsor information

Organisation La Sapienza University of Rome (Italy)

Sponsor details Department of Anaesthesia and Critical Care Medicine 2nd Faculty of Medicine Sant'Andrea Hosptial via di Grottarossa 1035 Rome Italy 0135 roberto.arcioni@uniroma1.it

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