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Randomised, blinded, comparison of the respiratory depressant effects of morphine and S(+) ketamin infusions when used to provide postoperative analgesia in infants undergoing major surgery

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 16/04/2015	**Condition category** Surgery	[ ] 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
N0206152406

Study information

Scientific Title
Randomised, blinded, comparison of the respiratory depressant effects of morphine and S(+) ketamin infusions when used to provide postoperative analgesia in infants undergoing major surgery

Study objectives
Null hypothesis: the incidence of clinically significant respiratory depression in infants receiving equipotent analgesic doses of either S(+)ketamin or morphine by direct continuous infusion is the same.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised prospective blinded comparative study

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
Post operative pain

Interventions
S(+)ketamin or morphine by direct continuous infusion.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
S(+)ketamin and morphine

Primary outcome measure
To use the total number of respiratory depression episodes measured over the first 24 hours after return to the ward following surgery as primary clinical relevant variable.

Secondary outcome measures
Not provided at time of registration

Overall study start date
11/10/2004

Completion date
30/11/2007

Eligibility

Key inclusion criteria
70 infants aged less than 60 weeks post-conceptual age undergoing elective or urgent abdominal surgery who would not be expected to require postoperative artificial ventilation.

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Patients with severe CNS abnormalities
2. Patients with severe renal or hepatic dysfunction
3. Patients with post-conceptual age of <37 weeks
4. Patients requiring respiratory support preoperatively
5. Patients receiving epidural opioids or local anaesthetic drugs
6. Patients having apnoeas or periodic breathing preoperatively

Date of first enrolment
11/10/2004

Date of final enrolment
30/11/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Liverpool Children's Hospital NHS Trust
Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Royal Liverpool Children's NHS Trust (UK), 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