

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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised prospective blinded comparative study

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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

United Kingdom

England

Study participating centre

Royal Liverpool Children's Hospital NHS Trust

Liverpool

United Kingdom

L12 2AP

Sponsor information

Organisation

Department of Health

Funder(s)**Funder type**

Government

Funder Name

Royal Liverpool Children's NHS Trust (UK), NHS R&D Support Funding

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration