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

	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Surgery	Record updated in last year
	Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr PD Booker

Contact details

Anaesthesia Department Royal Liverpool Children's Hospital NHS Trust Eaton Road Liverpool United Kingdom L12 2AP

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 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

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