ISRCTN74484781 https://doi.org/10.1186/ISRCTN74484781

Do bupivacaine and ketamine give superior analgesis compared to bupivacaine alone when used in a caudal epidural in children undergoing umbilical hernia repair?

Submission date
12/09/2003

Registration date
12/09/2003

Last Edited
30/08/2012

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[_] 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

Contact name
Dr Lionel Davis

Contact details
ITU
Homerton University Hospital NHS Trust
Homerton Row
London
United Kingdom
E9 6SR
+44 (0)20 8452 5137

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0024108453

Study information

Scientific Title

Study objectives
Do bupivacaine and ketamine give superior analgesis compared to bupivacaine alone when used in a caudal epidural in children undergoing umbilical hernia repair?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

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
Pain management

Interventions
Randomised controlled trial:
A. Bupivacaine + Ketamine
B. Bupivacaine (standard treatment)

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure

Pain evaluation (Visual Analogue Scale [VAS] 'Oucher' Hanhallah Objective Pain Score) depending on age of the child.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2001

Completion date
30/06/2004

Eligibility

Key inclusion criteria
30 Study, 30 controls. American Society of Anesthesiologists (ASA) I & II children undergoing umbilical hernia repair as day cases at the Homerton and Royal London Hospitals.

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
60

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/09/2001

Date of final enrolment
30/06/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

ITU
London
United Kingdom
E9 6SR

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Homerton University Hospital NHS Trust (UK)

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