

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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 30/08/2012	<b>Condition category</b> Surgery	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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