# Perioperative stress response in infants undergoing cardiac surgery: a comparison of three alfentanil dosage regimens

Submission date	Recruitment status	[X] Prospectively registered
12/09/2003	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	Results
Last Edited	Condition category	[] Individual participant data
17/07/2012	Surgery	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr PD Booker

#### Contact details

Department of Anaesthesia Royal Liverpool Children's Hospital NHS Trust Eaton Road Liverpool United Kingdom L12 2AP +44 (0)151 228 4811 x 2220

# Additional identifiers

Protocol serial number N0206102381

# Study information

Scientific Title

## **Study objectives**

What is the smallest dose of alfentanil that minimises neuro-hormonal stress response in infants undergoing cardiac surgery?

## 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

## Study type(s)

**Not Specified** 

# Health condition(s) or problem(s) studied

Surgery: Stress

#### **Interventions**

Patients will be given one of three alfentanil dose regimens by random allocation. Serial blood sampling will be used to provide plasma for analysis of markers of neuro-hormonal response.

## Intervention Type

Procedure/Surgery

#### Phase

**Not Specified** 

## Primary outcome(s)

Plasma cortisol concentration 5 min following sternotomy.

# Key secondary outcome(s))

Not provided at time of registration

# Completion date

30/03/2007

# **Eligibility**

## Kev inclusion criteria

90 infants aged less than 1 year undergoing palliative or corrective surgery of congenital cardiac defects involving cardiopulmonary bypass.

# Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

## Age group

Not Specified

#### Sex

**Not Specified** 

## Key exclusion criteria

Not provided at time of registration

## Date of first enrolment

30/01/2004

## Date of final enrolment

30/03/2007

# Locations

## Countries of recruitment

**United Kingdom** 

England

## Study participating centre Department of Anaesthesia

Liverpool
United Kingdom
L12 2AP

# Sponsor information

## Organisation

Department of Health (UK)

# Funder(s)

## Funder type

Charity

### **Funder Name**

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

### Funder Name

Heartbeat

# **Results and Publications**

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration