# 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	Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr PD Booker

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

**Not Specified** 

## Participant information sheet

# 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 measure

Plasma cortisol concentration 5 min following sternotomy.

## Secondary outcome measures

Not provided at time of registration

# Overall study start date

30/01/2004

# Completion date

30/03/2007

# **Eligibility**

## Key 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** 

## Age group

**Not Specified** 

#### Sex

**Not Specified** 

## Target number of participants

90

## 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

England

United Kingdom

# Study participating centre Department of Anaesthesia

Liverpool United Kingdom L12 2AP

# 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

Charity

## **Funder Name**

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

## **Funder Name**

Heartbeat

# **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