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

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

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
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