

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	☒ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 17/07/2012	Condition category Surgery	☐ Individual participant data ☐ 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

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**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

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