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Thiopentone and ketamine versus isoflurane and fentanyl to maintain anaesthesia during cardiopulmonary bypass; effect on postoperative neuropsychological function. Neuropsychological Function after Coronary Artery Bypass Graft (CABG)

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[ ] 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 05/12/2014	**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
N0054119938

Study information

Scientific Title
Thiopentone and ketamine versus isoflurane and fentanyl to maintain anaesthesia during cardiopulmonary bypass; effect on postoperative neuropsychological function. Neuropsychological Function after Coronary Artery Bypass Graft (CABG)

Study objectives
To compare neurophysiological function after maintaining anaesthesia for cardiopulmonary bypass (CPB) with either:
1.Thiopentone and ketamine, or
2. Isoflurane and fentanyl

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective randomised double-blind study

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
Surgery: Anaesthesia

Interventions

Only the anaesthetist will be aware of which treatment is being given but they will not be involved in gathering the primary outcome data. Patients will undergo standard neuropsychological assessments and neurological examinations before and after surgery.

Thiopentone and ketamine preserve neuropsychological function after CABG when compared to standard technique.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Thiopentone and ketamine versus isoflurane and fentanyl

Primary outcome measure
Assessment of neurological outcome, mood, personality and quality of life and correlations with any change in neuropsychological function will be made.

Secondary outcome measures
Not provided at time of registration

Overall study start date
18/10/2002

Completion date
01/03/2004

Eligibility

Key inclusion criteria
1. All patients scheduled for elective CABG under the care of two surgical/anaesthetic teams
2. Under 80 years of age
3. Do not have porphyria, severe unstable coronary artery disease (UCAD) or who have hypersensitivity to any of the study drugs or central nervous system (CNS) disease.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment
18/10/2002

Date of final enrolment
01/03/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Liverpool NHS Trust
Liverpool
United Kingdom
L14 3PE

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
The Cardiothoracic Centre Liverpool 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