ISRCTN78040136 https://doi.org/10.1186/ISRCTN78040136

Neuro-endocrine and immuno-systems activation during coronary surgery

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/03/2016	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 R Ascione

Contact details
c/o Research & Effectiveness Department
Level 1, The Old Building
Bristol Royal Infirmary
Malborough Street
Bristol
United Kingdom
BS2 8HW
+44 (0)117 928 3473
r&eoffice@ubht.swest.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0264149435

Study information

Scientific Title
Neuro-endocrine and immuno-systems activation during coronary surgery

Study objectives
To ascertain the effects of cardiopulmonary bypass (CPB) and cardioplegic arrest on the activation of the hypothalmic-pituatary-adrenal (HPA) system and on the relations between neuro endocrine and immune systems

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)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Coronary artery bypass grafting (CABG)

Interventions
Prospective randomised study patients randomised to:
1. With cardiopulmonary bypass
2. Without cardiopulmonary bypass

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure

To characterise the HPA system response during coronary surgery with or without cardiopulmonary bypass.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2004

Completion date
31/07/2005

Eligibility

Key inclusion criteria
80 patients admitted for first time coronary artery surgery suitable for on or off CPB surgery

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
80

Key exclusion criteria
1. Single vessel coronary disease
2. Emergency referral
3. Previous Coronary Artery Graft Bypass (CAGB)
4. Evidence of severe thoracic disease

Date of first enrolment
01/08/2004

Date of final enrolment
31/07/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
c/o Research & Effectiveness Department
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
United Bristol Healthcare NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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