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