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Optimal timing for Angiotensin Converting Enzyme (ACE) Inhibitor discontinuation in patients undergoing cardiac surgery on cardiopulmonary bypass.

Submission date 30/09/2004	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2004	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 29/08/2012	**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

Contact name
Mr A A A Ali

Contact details
Department of Cardiothoracic Surgery
Yorkshire Heart Centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX
+44 (0)7967 672729
r&d@leedsth.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0436130524

Study information

Scientific Title

Study objectives
There is some evidence that the continuation of ACE inhibitors until the time of surgery may lead to increased requirements of vasoconstrictor agents to maintain blood pressure. We aim to investigate this suggestion.

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Cardiovascular

Interventions
Patients will be randomised to discontinuing their ACE inhibitor 7 days preoperatively or continuing the medication until the morning of operation.

29/08/2012: Please note that this trial was abandoned before starting.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Angiotensin Converting Enzyme (ACE) Inhibitor

Primary outcome measure
Primary outcome measures are those relating to the presence and treatment of perioperative and postoperative hypotension. Systemic vascular resistance will be measured via Swan-Ganz catheterisation preoperatively and at fixed intervals in the postoperative period. In addition the requirement of vasoconstrictor agents as well as the duration of their use and the total dose administered will be documented.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2003

Completion date
01/02/2006

Eligibility

Key inclusion criteria
Patients undergoing elective first time coronary artery surgery on the ACE inhibitor Ramipril will be eligible for the study.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Exclusion criteria are redo procedures and poor left ventricular function (Ejection Fraction <30%).

Date of first enrolment
01/06/2003

Date of final enrolment
01/02/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Cardiothoracic Surgery
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals 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