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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

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration