

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/08/2012	Condition category Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Primary study design

Interventional

Study design

Randomised controlled trial

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