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

Submission date	Recruitment status	Prospectively registered
30/09/2004	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2004	Stopped	Results
Last Edited	Condition category	☐ Individual participant data
29/08/2012	Surgery	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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