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Modulation of ischaemic induced cardiac dysfunction by remote pre-conditioning

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/08/2016	Circulatory System	

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
N0544112277

Study information

Scientific Title
Modulation of ischaemic induced cardiac dysfunction by remote pre-conditioning

Study objectives
The effect of remote preconditioning on post-ischaemic left ventricular dysfunction (stunning) after dobutamine will be assessed by echocardiography in patients with single vessel coronary disease awaiting coronary angioplasty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridge LREC, September 2001

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiovascular: Single vessel coronary disease

Interventions
Myocardial ischaemia is common in patients with coronary artery disease (CAD) and may be asymptomatic and occur during everyday life. Brief episodes of demand ischaemia, where the increase in coronary blood supply is insufficient to meet the increase in cardiac work, may result in both an adaptive change in metabolism and a transient reduction in regional left ventricular contractile function (stunning). The changes in contractile function can be assessed by echocardiography and from the basis of dobutamine stress echocardiography that is a well-validated non-invasive technique for the diagnosis and assessment of patients with CAD. Episodes of ischaemia in a remote organ (such as a limb) may modify the myocardial response to ischaemia and this study will use this technique to assess the myocardial response to dobutamine in patients with single vessel CAD. Using a randomised cross-over design, a baseline dobutamine stress study will be performed to confirm that stunning can be induced, with two further studies with and without remote preconditioning. The latter will be induced by inflating a blood pressure cuff in the non-dominant arm to 30 mmHg above systolic blood pressure for 5 min, deflated for 5 min and then repeated three times. At the end of these three cycles (that have previously been performed uneventfully in volunteers) the dobutamine stress echocardiogram will be performed using a standard clinical protocol with myocardial imaging every 3 min during the incremental increases in dobutamine dosage. Imaging will be repeated every 3 min for 3 h after the end of the dobutamine infusion.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Dobutamine

Primary outcome(s)
Added July 2008:
Change in ejection fraction after remote preconditioning, compared to baseline.

Key secondary outcome(s))
Added July 2008:
1. Segmental LV wall tissue velocities
2. Rate pressure product
3. ECG ST deviation and chest pain score after remote preconditioning, compared to baseline

Completion date
01/04/2005

Eligibility

Key inclusion criteria
Added July 2008:
1. Able to consent
2. Age >18
3. Coronary artery disease
4. Normal left ventricular function

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Added July 2008:
1. Diabetes mellitus
2. Valvular heart disease
3. Permanent pacemaker
4. Left bundle branch block (LBBB) on electrocardiogram (ECG)
5. Myocardial infarction in the preceding 3 months
6. Not in sinus rhythm or taking nicorandil or glibenclamide medication

Date of first enrolment
02/04/2002

Date of final enrolment
01/04/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Addenbrooke's NHS Trust
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

Results article		01/04/2010		Yes	No
Results article	results	01/09/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes