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A prospective, randomised, controlled trial to study the effect of verapamil and adenosine on the TIMI frame count

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
05/05/2010

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0227164222

Study information

Scientific Title

Study objectives
To study if the use of verapamil and adenosine will result in improved blood flow through the heart arteries, assessed by the TIMI frame count.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Angiography and/or angioplasty

Interventions
Patients undergoing coronary angiography with a view to urgent or emergency angioplasty will be consented and will be given a patient information leaflet. Patients will be randomised if their coronary arteries show evidence of the slow-flow phenomenon and all patients undergoing angiography and/or angioplasty in the setting of an acute coronary syndrome will also be randomised. Normal saline, verapamil or adenosine will be administered and pictures of the heart arteries will be taken. At the end of the procedure the TIMI frame count (number of picture frames required for the dye to travel from the top end of the artery to the bottom end) will be calculated.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
verapamil and adenosine

Primary outcome measure
1. Improvement in TIMI frame count.
2. Post-procedural left ventricular function (measured by echocardiography).
3. Speed and extent of ST segment recovery.
4. Cardiac enzyme measurements.

Secondary outcome measures
Not provided at time of registration

Overall study start date
07/05/2003

Completion date
07/05/2004

Eligibility

Key inclusion criteria
35 in each group, total 105 patients undergoing angiography and/or angioplasty in the setting of an acute coronary syndrome.
Patients will be randomised if their coronary arteries show evidence of the slow-flow phenomenon and all patients undergoing angiography and/or angioplasty in the setting of an acute coronary syndrome will also be randomised.
Patients who are listed for elective or emergency angiography and/or angioplasty will be suitable for the study.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
105

Key exclusion criteria
1. Asthmatics
2. Patients with renal impairment
3. Those with left main stem disease
4. Patients with a BP<90mmHg and with a heart rate of >100 bpm
5. Patients with heart block

Date of first enrolment
07/05/2003

Date of final enrolment
07/05/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The James Cook University Hospital
Cleveland
United Kingdom
TS4 3BW

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
South Tees 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2006		Yes	No