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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

**Protocol serial number**
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

## Primary study design
Interventional

## Study design
Randomised controlled trial

## Study type(s)
Not Specified

## 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(s)
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.

## Key secondary outcome(s)

Not provided at time of registration

### 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

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex
Not Specified

### 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
United Kingdom

England

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

# Sponsor information

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

# Funder(s)

**Funder type**
Government

**Funder Name**
South Tees Hospitals NHS Trust (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 article | results | 01/09/2006 | | Yes | No |