

# Combined angioplasty and pharmacological intervention versus thrombolysis alone in acute myocardial infarction (CAPITAL AMI Study)

<b>Submission date</b> 05/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/04/2008	<b>Condition category</b> Circulatory System	<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

**Contact name**  
Dr Michel Robert Le May

**Contact details**  
University of Ottawa Heart Institute  
40 Ruskin Street  
H-150  
Ottawa  
Canada  
K1Y4W7  
+1 613 761 4980 Or 4223  
mlemay@ottawaheart.ca

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## Study information

### Scientific Title

### Acronym

CAPITAL AMI

### Study objectives

To assess the effectiveness of a strategy combining thrombolysis followed by immediate angiography with intentional stenting of the IRA, compared with thrombolysis alone, for the treatment of high risk AMI patients

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

University of Ottawa Heart Institute Human Research Ethics Board, 10/08/2000

### 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

Acute myocardial infarction (AMI)

### Interventions

Tenecteplase (TNKase) plus percutaneous coronary intervention (PCI) versus Tenecteplase (TNKase) alone

### Intervention Type

Other

### Phase

Not Specified

### **Primary outcome measure**

The primary end point will be the composite of the following clinical events:

1. Death
2. Recurrent myocardial infarction
3. Recurrent unstable ischemia
4. Stroke, measured at 6 months after the index AMI

### **Secondary outcome measures**

Determine if combined pharmacological and interventional strategy compared to pharmacological alone:

1. Decreases the frequency of the following individual clinical events:
  - a. Death
  - b. Recurrent myocardial infarction
  - c. Recurrent unstable ischemia
  - d. Stroke
2. Improves ST-segment elevation resolution, a surrogate marker of clinical efficacy
3. Decreases the need for subsequent revascularization (PTCA of the target vessel, PTCA of a non-target vessel, or CABG)
4. Decreases the frequency of recurrent unstable ischemia
5. Decreases the frequency of CHF and cardiogenic shock
6. Decreases the frequency of CHF at follow-up
7. Improves CCS angina class at follow-up
8. Is economically attractive
9. Influences subsequent quality of life
10. Is feasible in community hospitals without an on-site catheterization laboratory i.e. patients with large AMI who are initially treated with thrombolytic therapy can be transferred safely and in a timely fashion to a centre equipped with a catheterization laboratory for interventional therapy

### **Overall study start date**

01/07/2001

### **Completion date**

31/07/2004

## **Eligibility**

### **Key inclusion criteria**

1. Ischemic chest discomfort of  $\geq 30$  minutes duration
2. Aged 18 years and older, either sex
3. Onset of Chest Pain  $\leq 6$  hours prior to entry into the study and one of the following high risk criteria:
  - 3.1. Anterior AMI with ST-segment elevation  $\geq 2$  mm in each of at least contiguous precordial leads (V1-V6)
  - 3.2. Extensive nonanterior AMI on a standard 12 lead electrocardiogram (ECG) defined as:
    - 3.2.1. Eight or more leads with  $\geq 0.1$  mV ST elevation or depression, or both; ST segment elevation of  $>1$  mm (0.1 mV) must be present in two or more contiguous electrocardiographic leads
    - 3.2.2. Sum of ST-segment elevation  $>20$  mm measured 60 msec after the J-point
4. Killip 3 and either ST segment elevation of  $>1$  mm (0.1 mV) in two or more contiguous

electrocardiographic leads (on a standard 12 lead ECG) or left bundle branch block not known to be old

5. Systolic blood pressure <100 mmHg and either ST segment elevation of >1 mm (0.1mV) in two or more contiguous electrocardiographic leads (on a standard 12 lead ECG) or left bundle branch block not known to be old

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

170

### **Key exclusion criteria**

1. Low risk AMI defined as having the absence of high risk features defined above
2. Acute bleeding
3. History of stroke or central nervous system (CNS) damage
4. Major surgery or trauma within the past 3 months
5. Uncontrolled hypertension (SBP  $\geq 200$  mmHg and/or DBP  $\geq 120$  mmHg despite treatment)
6. Prolonged (>10 min) cardiopulmonary resuscitation
7. Inadequate vascular access
8. Previous coronary artery bypass graft (CABG)
9. PTCA within the last 6 months
10. Abciximab (ReoPro TM) or other GP IIb/IIIa antagonists within the preceding 7 days
11. Coagulation disorder (i.e. international normalized ratio (INR) >2.0, platelets <100,000/mm<sup>3</sup>, or hematocrit <30%)
12. Current warfarin treatment
13. Within 6 hours randomization, either:
  - a. Standard unfractionated heparin (heparin sodium)  $\geq 5000$  IU
  - b. A subcutaneous therapeutic dose of any low molecular weight heparin
14. Intolerance to aspirin
15. Other medical condition that is likely to result in death within 12 months
16. Participation in a study with another investigational device or drug <4 weeks
17. Pregnancy
18. Known severe renal impairment (creatinine >300  $\mu\text{mol/l}$ )
19. Sustained hypotension defined as SBP <90 mmHg or the need for intravenous (IV) inotropes and/or intraaortic balloon counter pulsation to support the blood pressure
20. Known severe contrast (dye) allergy
21. Inability to provide informed consent

### **Date of first enrolment**

01/07/2001

### **Date of final enrolment**

31/07/2004

## Locations

### Countries of recruitment

Canada

### Study participating centre

University of Ottawa Heart Institute

Ottawa

Canada

K1Y4W7

## Sponsor information

### Organisation

University of Ottawa Heart Institute (Canada)

### Sponsor details

40 Ruskin street

Ottawa

Canada

K1Y 4W7

### Sponsor type

Not defined

### ROR

<https://ror.org/03c4mmv16>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: DCT-48205)

### Funder Name

## 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