

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

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

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Additional identifiers

Protocol serial number
DCT-48205

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

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

Completion date

31/07/2004

Eligibility

Key inclusion criteria

- 1. Ischemic chest discomfort of ≥ 30 minutes duration
- 2. Aged 18 years and older, either sex
- 3. Onset of Chest Pain ≤ 6 hours prior to entry into the study and one of the following high risk criteria:
 - 3.1. Anterior AMI with ST-segment elevation ≥ 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 ≥ 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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 ≥ 200 mmHg and/or DBP ≥ 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 $<100,000$ /mm³, or hematocrit $<30\%$)
12. Current warfarin treatment
13. Within 6 hours randomization, either:
 - a. Standard unfractionated heparin (heparin sodium) ≥ 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)

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

CIHR Industry-Partnered Program with Hoffmann La-Roche Limited (Canada) and Guidant Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration