ISRCTN44258879 https://doi.org/10.1186/ISRCTN44258879

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/09/2005	**Overall study status** Completed	
Last Edited 18/04/2008	**Condition category** Circulatory System	

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

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

Study design
Randomised controlled trial

Primary study design
Interventional

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 infraction
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 /mm^3, 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 µmol/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