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Trial of routine angioplasty and stenting after fibrinolysis to enhance reperfusion in acute myocardial infarction: The TRANSFER-AMI trial

Submission date 09/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/09/2005	**Overall study status** Completed	
Last Edited 25/02/2009	**Condition category** Circulatory System	

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
NCT00164190

Secondary identifying numbers

MCT-69798

Study information

Scientific Title
Routine angioplasty and stenting after fibrinolysis to enhance reperfusion in acute myocardial infarction: a randomised controlled trial

Acronym
TRANSFER-AMI

Study objectives
A strategy of routine transfer of patients with AMI to an angioplasty centre immediately after thrombolysis for coronary angiography and percutaneous intervention is associated with a significantly lower incidence of the composite of death, reinfarction, recurrent ischaemia, heart failure and shock at 30 days compared with the conventional strategy of thrombolysis with transfer reserved for failed reperfusion and/or development of shock.

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Michael's Hospital (Toronto) - Research Ethics Board Office of Research Administration approved on 21st July 2003

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute Myocardial Infarction

Interventions
1. Facilitated Percutaneous Coronary Intervention (PCI) strategy: Full-dose weight-adjusted tenecteplase + unfractionated heparin or Enoxaparin (30 mg IV bolus + 1 mg/kg subcutaneously [sc]), followed by immediate transfer for cardiac catheterisation PCI
2. Thrombolysis with Provisional Rescue PCI: Full-dose weight-adjusted tenecteplase +

unfractionated heparin or Enoxaparin (30 mg IV bolus + 1 mg/kg sc), bedside clinical assessment of reperfusion at 60 - 90 minutes, rescue PCI for patients with evidence of failed reperfusion

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
30-day composite of:
1. Death (all cause)
2. Reinfarction
3. Recurrent ischaemia
4. New or Worsening Congestive Heart Failure, including readmission for heart failure
5. Development of cardiogenic shock requiring inotropic support or intra-aortic balloon pump insertion

Secondary outcome measures
1. The incidence of major/severe bleeding, as defined by the TIMI and GUSTO bleeding classifications in the first 30 days
2. The proportion of patients with complete (greater than 70%) and partial (30 - 70%) ST-segment resolution from the qualifying ECG to 6 hours after randomisation
3. Infarct size as assessed by QRS scoring system on the 180 minute 12-lead electrocardiogram
4. The composite of death or reinfarction at 6 months
5. The composite of death or reinfarction at 1 year
6. Health costs

Overall study start date
07/10/2004

Completion date
31/08/2007

Eligibility

Key inclusion criteria
1158 persons with acute myocardial infarction of both sex, 18 years and older. Patients greater than or equal to 18 years old who present within 12 hours of symptom onset with more than 30 minutes of continuous symptoms of an acute myocardial infarction, with high risk characteristics, defined as either:
1. 2 mm ST-segment elevation in 2 or more contiguous anterior leads
2. 1 mm ST-segment elevation in 2 or more contiguous inferior leads with either:
2.1. Systolic blood pressure less than 100 mmHg
2.2. Heart Rate greater than 100/minute
2.3. Killip Class II - III
2.4. 2 mm ST-segment depression in anterior leads
2.5. 1 mm ST-segment elevation in right-sided lead V4 (V4R), indicative of right ventricular involvement

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1158

Key exclusion criteria
1. Left Bundle Branch Block
2. Cardiogenic Shock (Killip Class IV)
3. Active bleeding or known haemorrhagic diathesis
4. Availability of Primary PCI with door-to- balloon time = 60 minutes
5. Time from thrombolysis to initiation of consent process greater than 30 minutes
6. Use of thrombolytic agent other than tenecteplase for index event
7. Major surgery, biopsy of parenchymal organ, or significant trauma in the past 6 weeks
8. Systolic blood pressure greater than 200 mmHg or diastolic greater than 110 mmHg after arrival to the hospital and before enrolment
9. Concomitant use of oral anticoagulants (e.g. warfarin) with International Normalized Ratio (INR) of greater than 2
10. Recent non-compressible vascular puncture
11. History of central nervous system structural damage (e.g. aneurysm, neoplasm, arteriovenous malformation, stroke) at any time, or transient ischaemic attack within the last year
12. History of heparin-induced thrombocytopenia
13. Documented allergy to aspirin
14. Participation in other clinical research studies involving experimental therapies including drugs or devices within 7 days of enrolment or prior participation in this study
15. Inability to cooperate with the protocol or undergo cardiac catheterisation
16. Other serious illness (e.g. active cancer, significant hepatic or renal disease)
17. Percutaneous coronary intervention within the prior month
18. Previous bypass surgery
19. Pregnancy

Date of first enrolment
07/10/2004

Date of final enrolment
31/08/2007

Locations

Countries of recruitment
Canada

Study participating centre
Interventional Cardiologist, Southlake Regional Health Centre
Newmarket, Ontario
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L3Y 2R2

Sponsor information

Organisation
University of Toronto (Canada)

Sponsor details
27 King's College Circle
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M5S 1A1

Sponsor type
University/education

Website
http://www.utoronto.ca/

ROR
https://ror.org/03dbr7087

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-69798)

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	01/01/2008		Yes	No