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TiMing of Intervention in patients with Acute Coronary Syndromes

Submission date	Recruitment status	[_] Prospectively registered
27/11/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/11/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/04/2019	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00552513

Secondary identifying numbers
MCT-79654

Study information

Scientific Title
An International randomised trial of early versus delayed invasive strategies in patients with non-ST segment elevation acute coronary syndromes

Acronym
TIMACS

Study objectives
1. In patients with acute coronary syndromes (ACS), a strategy of routine early coronary angiography (less than 24 hours after randomisation) and intervention is superior to a strategy of delayed coronary angiography (more than 36 hours after randomisation) and intervention in preventing major cardiovascular events
2. In patients with ACS, a delayed invasive strategy will result in lower rates of major bleeding versus a strategy of early angiography and revascularisation
3. A strategy of early coronary angiography and revascularisation will be more cost effective than a strategy of delayed coronary angiography and revascularisation

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Board of the Hamilton Health Sciences/McMaster Health Sciences, Hamilton, Ontario, Canada, 26/05/2005
2. Comité de Ética em Pesquisa, Santa Casa de Belo Horizonte, Belo Horizonte, Brazil, 29/05/2006
3. Comité d'Ethique Médicale, Centre Hospitauer Regional De Huy, De Huy, Belgium, 12/10/2005
4. Ethics Committee of the Middle Slovak Institute of Cardiovascular Diseases, Banska Bistrica, Slovakia, 26/10/2006
5. University Clinical Emergency Hospital Mures Clinic of Cardiology, Targu Mures, Romania, 01/11/2006

Study design

Therapeutic management strategy and procedures intervention type randomised parallel two-armed multicentre multi-national trial with accessor blinding

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute coronary syndromes (unstable angina and non-ST segment elevation myocardial infarction)

Interventions
Early intervention:
Coronary angiography and intervention as soon as possible (within 24 hours of randomisation).

Delayed intervention:
Coronary angiography and intervention any time after 36 hours after randomisation.

Intervention Type
Procedure/Surgery

Primary outcome measure
The first occurrence of the composite death/myocardial (re-)infarction/stroke up to day 180.

Secondary outcome measures
1. The composite of death, myocardial (re-)infarction, stroke, refractory ischaemia or repeat revascularisation at 180 days
2. The first occurrence of any component of the composite of death myocardial infarction and refractory ischaemia until day 14, 30, 90 and at six months (day 180)
3. Stroke at 30 days and 180 days
4. Need for mechanical or pharmacological coronary revascularisation (i.e., percutaneous coronary intervention [PCI], coronary artery bypass graft [CABG], thrombolysis) at days 30, 90 and 180 days

Overall study start date
15/06/2005

Completion date
01/05/2008

Eligibility

Key inclusion criteria
1. Patients presenting or admitted to hospital with symptoms suspected to represent an acute coronary syndrome (unstable angina or MI without persistent ST elevation), i.e. clinical history consistent with new onset, or a worsening pattern, of characteristic ischaemic chest pain or ischaemic symptoms occurring at rest or with minimal activity (lasting longer than five minutes or requiring sublingual nitroglycerin for relief of the pain)
2. Able to randomise within 24 hours of the onset of the most recent episode of symptoms
3. At least two of the three following additional criteria:
3.1. Age more than or equal to 60 years, either sex
3.2. Troponin T or I or creatine kinase - myocardial bands (CK-MB) above the upper limit of normal for the local institution
3.3. Electrocardiogram (ECG) changes compatible with ischaemia (i.e., ST depression at least 1 mm in two contiguous leads or T wave inversion mroe than 3 mm or any dynamic ST shift or transient ST elevation)
4. Written informed consent dated and signed

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
4000

Key exclusion criteria
1. Age less than 21 years
2. Not a suitable candidate for revascularisation
3. Co-morbid condition with life expectancy less than six months

Date of first enrolment
15/06/2005

Date of final enrolment
01/05/2008

Locations

Countries of recruitment
Argentina

Belgium

Brazil

Bulgaria

Canada

Chile

China

Czech Republic

France

Germany

Greece

India

Poland

Romania

Slovakia

Slovenia

Switzerland

United States of America

Study participating centre
Hamilton Health Sciences
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Sponsor type
Research organisation

Website
http://www.phri.ca

ROR
https://ror.org/03kwaeq96

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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?
Basic results				No	No
Results article	results	21/05/2009	10/04/2019	Yes	No