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Clinical Outcomes Utilising Revascularisation and Aggressive Drug Evaluation

Submission date	Recruitment status	[_] Prospectively registered
26/09/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/01/2014	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
NCT00007657

Secondary identifying numbers
PCT-15191

Study information

Scientific Title

Acronym
COURAGE

Study objectives
Primary Hypothesis:
The strategy of Percutaneous Coronary Intervention (PCI) plus intensive medical therapy will be superior to intensive medical therapy alone in reducing all cause mortality, non-fatal Myocardial Infarction (MI) or biomarker positive (troponin) acute coronary syndrome patients with documented myocardial ischaemia who meet an American Heart Association (AHA) task force Class I indication for PCI.

Secondary Hypothesis:
Resource utilisation and Quality Of Life (QOL) comparisons and hospitalisation for unstable angina will be superior in PCI plus medical therapy compared to medical therapy alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Research Ethics Board of McMaster University on the 8th September 1999.

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
Myocardial Ischaemia

Interventions
Both groups: Intensive medical therapy
Experimental group: Percutaneous coronary intervention beside the intensive medical therapy

Trial details received: 12 September 2005

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Composite of all causes mortality, non-fatal MI and hospitalised acute coronary syndrome with biomarkers (troponin) positively.

Secondary outcome measures
1. Quality of life, assessed at regular intervals during the trial
2. Resource utilisation: Comprehensive information on health care used by COURAGE participants, including the direct in-hospital cost of PCI, other healthcare costs, and indirect costs incurred by patients
3. Hospitalisation for unstable arginia with negative biomarkers

Overall study start date
01/06/1999

Completion date
30/06/2006

Eligibility

Key inclusion criteria
Patients (greater than or equal to 18 years old, either sex) eligible for inclusion in COURAGE will comprise all but very high-risk subjects, and will include those with chronic angina pectoris (Canadian Cardiovascular Society [CCS] Class I - III), uncomplicated MI, and asymptomatic (or 'silent') myocardial ischaemia. Patients may have single - or multi-vessel coronary artery disease and may have had prior bypass graft surgery. It is important to emphasize that as many types of Coronary Heart Disease (CHD) patients as possible - reflecting the spectrum of patients encountered in contemporary clinical practice - will be enrolled in COURAGE.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2546

Key exclusion criteria
1. Unstable angina and symptoms refractory to maximal oral and intravenous medical therapy (persistent CCS Class IV)
2. Post-MI course complicated by persistent rest angina, shock, and persistent CHF for which the need or likelihood of urgent myocardial revascularisation is high
3. Coronary angiographic exclusions:
3.1. Patients with no prior Coronary Artery Bypass Graft (CABG) and left main coronary disease greater than 50%
3.2. Coronary arteries technically unsuitable or hazardous for PCI
3.3. Patients with non-significant coronary artery disease in whom PCI would not be considered appropriate or indicated
3.4. Ejection fraction less than 30%, except less than 35% if patients has three-vessel disease including greater than 70% Left Anterior Descending (LAD) proximal stenosis
3.5. Cardiogenic shock
3.6. Pulmonary edema or CHF unresponsive to standard medical therapy
3.7. CABG or PCI within the last 6 months
3.8. Concomitant valvular heart disease likely to require surgery or affect prognosis during follow-up
3.9. Congenital or primary cardiac muscle disease likely to affect prognosis during follow-up
3.10. Resuscitated out-of-hospital sudden death or symptomatic sustained or non-sustained ventricular tachycardia
3.11. Significant systemic hypertension (Blood Pressure [BP] greater than 200/100 mmHg) unresponsive to medical therapy

Date of first enrolment
01/06/1999

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
Canada

United States of America

Study participating centre
3U4 McMaster University Medical Centre
Hamilton
Canada
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Sponsor information

Organisation
Department of Veteran Affairs, U.S. Federal Government and McMaster University Faculty of Health Sciences (Canada)

Sponsor details
Ms Marie Townsend
Administrator
Research Programs
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Sponsor type
Not defined

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Industry

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: PCT-15191)

Funder Name
Cooperative Studies Program of the Department of Veterans Affairs Office of Research and Development (USA)

Funder Name
Merck and Co. Inc. (USA)

Funder Name
Pfizer Pharmaceuticals (USA)

Funder Name

Bristol-Meyers Squibb Medical Imaging (USA)

Funder Name
Fujisawa Pharmaceuticals (UK)

Funder Name
Kos Pharmaceuticals (USA)

Funder Name
Datascope (USA)

Funder Name
AstraZeneca (USA)

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Key Pharmaceuticals (Australia)

Funder Name
Sanofi-Aventis (USA)

Funder Name
First Horizon (USA)

Funder Name
Nycomed Amersham (UK)

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?
Protocol article	protocol	15/01/2007		Yes	No
Results article	results	29/09/2009		Yes	No
Results article	results	30/03/2010		Yes	No
Results article	results	01/02/2014		Yes	No