

Clinical Outcomes Utilising Revascularisation and Aggressive Drug Evaluation

Submission date 26/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 26/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 23/01/2014	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00007657

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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 angina with negative biomarkers

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

L8N 3Z5

Sponsor information

Organisation

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

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, AZ

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/09/2009		Yes	No
Results article	results	30/03/2010		Yes	No
Results article	results	01/02/2014		Yes	No
Protocol article	protocol	15/01/2007		Yes	No