

Clinical Trial: COURAGE - Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation

CT00432

Sponsoring Company:

- Department of Veterans Affairs
- Medical Research Council of Canada
- Merck & Co., Inc.

Objective:

- To evaluate whether percutaneous coronary intervention (PCI) (optimal catheter-based coronary revascularization) plus intensive medical therapy is superior to intensive medical therapy alone using the combined endpoint of all-cause mortality or nonfatal MI.

Trial Status:

- Completed

Trial Phase:

- N/A

Inclusion Criteria:

| PCI Group (%) | Medical Therapy Group (%) |
|---------------|---------------------------|
| 19.0 | 18.5 |
| 20.0 | 19.5 |
| 12.4 | 11.8 |
| 7.6 | 8.3 |
| 13.2 | 12.8 |
| 27.6 | 27.0 |
| 2.1 | 1.8 |
| 23.1 | 22.6 |

- Very high-risk subjects including those with chronic angina pectoris (Canadian Cardiovascular Society [CCS] Class I-III), uncomplicated MI, cooled down ACS, and asymptomatic (or "silent") myocardial ischemia
- Patients may have single- or multi-vessel coronary artery disease and may have had prior bypass graft surgery or PCI.

Exclusion Criteria:

- Uncontrolled unstable angina
- Complicated post-MI course
- Revascularization within 6 months
- Ejection fraction <30%
- Cardiogenic shock/severe heart failure
- History of sustained or symptomatic VT/VF

Primary Endpoints:

- All cause mortality
- Nonfatal MI

PI:

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PI Study Site:

- Christiana Care HealthSystem, 4755 Ogletown-Stanton Rd., Newark, DE 19718

Enrollment:

- 5,358

Trial Start Date:

- January 1999

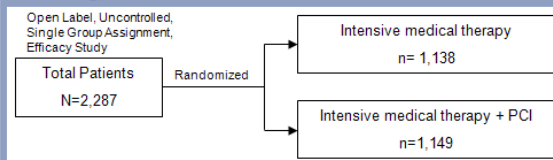
Trial Publication Date*:

- 03/26/2007

*The date is in the following format: MM/DD/YYYY

Trial Design:

Open Label, Uncontrolled, Single Group Assignment, Efficacy Study



Results:

| Primary and Secondary Outcomes | | Hazard Ratio (95% CI) | | P Value |
|---------------------------------|-----------|-----------------------|--------------------|---------|
| Outcome | PCI Group | Medical Therapy Group | | |
| Death & Nonfatal MI | 211 | 202 | 1.05 (0.87 - 1.27) | 0.62 |
| Death | 88 | 74 | | |
| Reinfarction/MI | 30 | 9 | | |
| Spontaneous MI | 108 | 110 | | |
| Death, MI, & Stroke | 222 | 213 | 1.05 (0.84 - 1.32) | 0.62 |
| Hospitalization for ACS | 135 | 125 | 1.07 (0.84 - 1.37) | 0.56 |
| Death | 88 | 95 | 0.87 (0.65 - 1.16) | 0.38 |
| Cardiac | 25 | 25 | | |
| Other | 40 | 51 | | |
| Unknown | 17 | 19 | | |
| Total Nonfatal MI | 143 | 128 | 1.13 (0.89 - 1.43) | 0.33 |
| Reinfarction/MI | 30 | 9 | | |
| Spontaneous MI | 108 | 110 | | |
| Death, MI, & ACS | 294 | 288 | 1.03 (0.90 - 1.17) | 0.52 |
| Stroke | 22 | 14 | 1.56 (0.80 - 3.04) | 0.18 |
| Revascularization (PCI or CABG) | 228 | 348 | 0.60 (0.51 - 0.71) | <0.001 |

Scores on the Seattle Angina Questionnaire from Baseline to 36 Months.

| Domain | PCI plus OMT | | OMT | | P Value | Missing Data | |
|----------------------------|--------------|-----------------|-------|-----------------|---------|------------------|---------|
| | Score | No. of Patients | Score | No. of Patients | | PCI plus OMT (%) | OMT (%) |
| Physical Limitation | | | | | | | |
| Baseline | 66±25 | 939 | 66±25 | 939 | 0.58 | 18 | 18 |
| 1 Month | 73±24 | 850 | 70±24 | 850 | 0.003 | 26 | 25 |
| 3 Month | 76±24 | 852 | 72±23 | 855 | 0.004 | 24 | 24 |
| 6 Month | 77±23 | 878 | 72±24 | 820 | <0.001 | 21 | 25 |
| 12 Month | 75±24 | 844 | 73±24 | 812 | 0.21 | 24 | 25 |
| 24 Month | 74±24 | 745 | 72±24 | 735 | 0.16 | 26 | 26 |
| 36 Month | 74±24 | 573 | 74±24 | 583 | 0.68 | 33 | 32 |
| Angina Stability | | | | | | | |
| Baseline | 54±33 | 953 | 53±32 | 947 | 0.56 | 17 | 17 |
| 1 Month | 81±26 | 866 | 73±28 | 873 | <0.001 | 24 | 23 |
| 3 Month | 77±28 | 860 | 73±27 | 860 | 0.002 | 23 | 23 |
| 6 Month | 76±28 | 880 | 73±27 | 880 | 0.32 | 27 | 27 |
| 12 Month | 77±28 | 880 | 73±27 | 880 | 0.32 | 27 | 27 |
| 24 Month | 77±28 | 880 | 73±27 | 880 | 0.32 | 27 | 27 |
| 36 Month | 77±28 | 880 | 73±27 | 880 | 0.32 | 27 | 27 |
| Quality of Life | | | | | | | |
| Baseline | 88±15 | 971 | 86±16 | 956 | 0.008 | 16 | 16 |
| 1 Month | 92±12 | 873 | 88±15 | 882 | <0.001 | 24 | 22 |
| 3 Month | 92±12 | 869 | 90±14 | 873 | <0.001 | 22 | 22 |
| 6 Month | 92±13 | 894 | 90±14 | 839 | 0.007 | 19 | 23 |
| 12 Month | 92±12 | 861 | 90±14 | 829 | 0.002 | 20 | 22 |
| 24 Month | 92±13 | 761 | 92±13 | 740 | 0.35 | 24 | 26 |
| 36 Month | 92±12 | 586 | 92±11 | 593 | 0.78 | 31 | 31 |

Conclusion:

- PCI did not reduce the risk of death, MI, or other major cardiovascular events when added to optimal medical therapy as an initial management strategy in patients with stable coronary artery disease. PCI resulted in better angina relief during most of the follow-up period. However medical therapy was also remarkably effective, with no between-group difference in angina-free status at 5 years
- The authors concluded that "the COURAGE trial showed that patients with chronic coronary disease may expect relief from angina whether they are treated with PCI plus optimal medical therapy or with optimal medical therapy alone. However, an initial strategy of PCI added to optimal medical therapy relieved angina and improved self-assessed health status to a greater extent than an initial strategy of optimal medical therapy alone for approximately 24 months. A greater benefit from PCI was observed in those patients with more severe and more frequent angina."

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