

Appendix D: Clinical Trials for Aims 2 and 3

Appendix D Table 1. Clinical Trial Databases used for External Validation of ACS CPMs.

Trial	Sample Size, Enrollment Years	Location	Population	Baseline Characteristics	Baseline Medications	Intervention	Primary Outcome	Effect size	Follow up Duration	Outcome events
AMIS ²	N=4524, 1975-1976	30 sites in US	Previous MI	Mean age 54.8 yrs 19% female	Aspirin: 74% Digitalis: 19% BB: 12% Antiarrhythmic: 10% Anti-HTN: 10% Nitroglycerin/nitrates: 39% Diuretics: 29% Lipid lowering: 5% Antihistamines: 3% Vitamins: 20% Gout medications: 3% Other drugs: 15%	Aspirin (1g) vs placebo	All-cause mortality	Aspirin vs placebo: 10.8% vs 9.7%; Cox adjusted Z value 0.02	Mean 3.2 yrs	Mortality: 10%
ENRICH ³	N=2481, 1996-2001	8 sites in US	Acute MI in past 28 days	Mean age 61 yrs 44% female 13% CABG hx 37% thrombolysis hx	Aspirin: 84% BB: 72% ACEi: 19% Anticoagulants: 19% Lipid lowering: 41%	CBT and SSRI or usual care	Recurrent MI or all-cause mortality	Usual care vs CBT and SSRIs: OR 1.01 (95% CI 0.86-1.18)	Mean 2.4 yrs	Mortality or nonfatal MI: 24%
MAGIC ⁴	N=6213, 1999-2002	278 sites in 14 countries	Acute STEMI	Median age 70 (63-76) yrs 45% female 3% PCI hx 2% CABG or PTCA hx	Aspirin: 93% BB: 53% ACEi: 52% Nitrates: 89% Anticoagulant: 87% Diuretic: 32% Inotrope or vasopressor: 8% Amiodarone: 4% Lipid lowering: 3% Digoxin: 3% Calcium channel blocker: 3% Glycoprotein IIb/III inhibitor: 2%	Intravenous Magnesium Sulfate or placebo	All-cause mortality	Magnesium vs placebo: OR 1.0 (95% CI 0.8–1.1)	30 days	Mortality: 15%
TIMI-II ⁵	N=3262, 1986-1988	50 sites in US	Suspected acute STEMI	Mean age 57 yrs 18% female	NR	Rt-PA and invasive strategy vs conservative strategy	All-cause mortality or recurrent MI	Invasive vs conservative treatment:	42 days	Mortality or reinfarction: 10%

Trial	Sample Size, Enrollment Years	Location	Population	Baseline Characteristics	Baseline Medications	Intervention	Primary Outcome	Effect size	Follow up Duration	Outcome events
								10.9% vs 9.7%; p=0.25		
TIMI-III ⁶	N=1473, 1989-1992	31 sites in US and Canada	Chest discomfort caused by ischemia in past 24 hours and evidence of CHD	Median age 59 ± 10 yrs 34% female 67% UA hx	BB: 34% Calcium antagonist: 43% Nitrates: 47% Heparin: 12%	TPA vs Placebo; Invasive vs Conservative treatment	Unfavorable outcome	TPA vs placebo: 54.2% vs 55.5%; p=0.61 Invasive vs conservative approach: 16.2% vs 18.1%; p=0.33	42 days	Unfavorable outcome: 55%

CHD, coronary heart disease; MI, myocardial infarction; STEMI, ST-elevation myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft surgery; PTCA, percutaneous transluminal coronary angioplasty; BB, beta-blockers; ACEi, angiotensin-converting enzyme inhibitors; CBT, cognitive behavioral therapy; SSRI, Selective serotonin reuptake inhibitor; rt-PA, recombinant tissue plasminogen activator; TPA, tissue plasminogen activator; yrs, years; hx, history; HTN, hypertension; UA, unstable angina; NR, not reported.