Steg PG, Lopez-Sendon J, Lopez de Sa E, Goodman SG, Gore JM, Anderson Jr FA, Himbert D, Allegrone J, Van de Werf F, for the GRACE Investigators. External Validity of Clinical Trials in Acute Myocardial Infarction. *Arch Intern Med* 2006 in press.

APPENDIX: Main eligibility criteria for the three randomized clinical trials

ASSENT-3

Inclusion criteria

- Symptom onset within 6 hours of hospital arrival
- New or presumed new ST-segment elevation ≥1 mm in ≥2 contiguous leads or left bundle branch block

Exclusion criteria

- Systolic blood pressure >180 mmHg or diastolic blood pressure >110 mmHg
- Use of glycoprotein IIb/IIIa inhibitors in the prehospital acute phase (in transit)
- History of major surgery or trauma within 2 weeks
- Any known history of stroke or transient ischemic attack
- Chronic or prehospital acute warfarin, low-molecular-weight heparin, or unfractionated heparin therapy
- Known renal insufficiency (serum creatinine >2.5 mg/dL for men and >2.0 mg/dL for women)
- Known history of resuscitated sudden cardiac death

Unable to determine in GRACE at admission (exclusion criteria): patients who actively participated in another investigative drug or device study within the previous 30 days, were previously enrolled in this study, or had unfractionated heparin or subcutaneous low-molecular-weight heparin given within 6 hours of hospital admission.

GUSTO V

Inclusion criteria

- Symptom onset between 30 minutes and 6 hours before hospital arrival
- New or presumed new ST-segment elevation ≥1 mm in ≥2 contiguous leads or left bundle branch block

Exclusion criteria

- Systolic blood pressure >180 mmHg and diastolic blood pressure >110mm Hg
- Chronic or prehospital acute warfarin therapy
- Any known history of stroke or transient ischemic attack
- Weight >120 kg

Unable to determine in GRACE at admission (exclusion criteria): planned catheter-based reperfusion, active bleeding, or noncompressible vascular puncture site, platelet count <100,000 cells/μL.

DANAMI-2

Inclusion criteria

- Symptom onset between 30 minutes and 12 hours before hospital arrival
- Cumulative ST-segment elevation ≥ 4 mm in ≥2 contiguous leads: sum of ST-segment deviations (of ≥1 mm in 2 contiguous leads) required in two locations (anterior, inferior, or lateral).

Exclusion criteria

- Known contraindication to thrombolytic therapy
- Left bundle branch block
- Prior coronary artery bypass graft surgery
- Serum creatinine >2.83 mg/dL
- Participating hospital does not have a catheterization laboratory
- Treated with metformin (chronic or in hospital); data not available for all patients
- Killip class IV (cardiogenic shock)

Unable to determine in GRACE at admission (exclusion criteria): acute myocardial infarction within previous 30 days, pulseless femoral arteries, noncardiac disease with life expectancy <12 months, persistent life-threatening arrhythmias, or need for mechanical ventilation.