The EMBRACE STEMI Study

Purpose: Evaluation of the safety and effectiveness of IV Bendavia (targets cellular mitochondria) to reduce reperfusion injury following ST-segment myocardial infarction (STEMI) in patients treated with PCI and stenting.

Trial Design: Phase 2a, randomized, double blinded, placebo-controlled, parallel safety and efficacy study comparing Bendavia (0.05 mg/kg/hr. for 1 hour) vs. placebo given before angioplasty in first-time STEMI for reperfusion injury. N=297. Lesion is proximal left anterior descending artery.

Primary Endpoint: infarct size over first 72 hours following PCI for STEMI measured by creatinine kinase-MB enzyme.

	Trial Results
Bendivia vs. placebo	Reduced scarring by 10% in first 72 hours – not statistically significant
	Primary and secondary endpoints - differences not statistically significant

Conclusions: Bendivia did not decrease the size of the infarction in this trial, but was found to be safe. The clinical outcomes were essentially the same for Bendavia or placebo. A trend noted during the initial hours after infusion Bendivia was a reduction in HF incidence that will require additional study.

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