Reviewer's report

Title: A Multicenter, Prospective, Randomized, Controlled Trial Evaluating the Safety and Efficacy of Intracoronary Cell Infusion Mobilized with Granulocyte colony-stimulating factor and Darbepoetin after Acute Myocardial Infarction: Study Design and Rationale of the 'MAGIC Cell-5-Combination Cytokine Trial'

Version: 3 Date: 3 December 2010

Reviewer: lawrence friedman

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a) Whether this is an early phase (I or II) trial or a late phase (III) is not stated. Because the primary outcome is not a clinical finding, but rather the result of an imaging test, I tend to think of it as an early phase study. The journal guidelines would generally not include such protocols. Here, however, I would favor publishing it, given that large, clinical outcome trials with these sorts of interventions are not yet common. It would be useful, though, if the investigators would indicate where they intend to go after this. Far too many agents that showed promise by improving ejection fraction turned out to be harmful when clinical outcomes (eg, death) were the endpoints in the phase III trials.

b) The authors say that they will use a “modified intention-to-treat analysis,” yet they indicate they will include all “who signed the written informed consent and were randomized to receive any part of active treatment.” Who among those randomized will not be included? And how will drop-outs be handled?

c) A one-sided alpha of 0.05 is not particularly rigorous. How was it justified?

d) There are a few grammatical/spelling errors (eg, page 5, line 6 from bottom—“is” should be “are”; page 6, “Amegen” should be “Amgen”; page 14, line 11—“to” after “Regarding” should be deleted). The authors should carefully re-read the manuscript for others.