Final Results for the Renew Trial: A Phase 3, Randomized, Double Blinded, Active-Controlled, Unblinded Standard of Care Study Assessing the Efficacy and Safety of Intramyocardial Autologous CD34+ Cell Administration in Patients with Refractory Angina

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Background
The Phase 2 ACT34 trial randomized 167 class III/IV refractory angina (RA) patients to autologous CD34+ stem cells (CD34+) vs placebo demonstrating an improvement in exercise time and reduction in angina providing the support for RENEW.

Methods
RENEW was a phase III trial designed to definitively determine the efficacy of granulocyte colony-stimulating factor (G-CSF) mobilized CD34+ for the treatment of RA pts (n=444) with evidence of ischemia on maximum anti-anginal therapy and without revascularization options. Pts were randomized 1:1:2 to open-label standard of care (SOC; n=28), blinded placebo (PL; n=27) (G-CSF mobilization, apheresis, and intramyocardial (IM) PL), or CD34+; n=57(G-CSF mobilization, apheresis, IM 1 x 10^5 CD34+ SCs/kg). The primary endpoint was change in ex time between CD34+ and PL pts.

Results
The trial was prematurely terminated by the sponsor due to financial considerations after enrollment of 112 pts. Mortality, at 2 years was lower in CD34+ treated pts: 3.7% vs 10% (PL) and 7.1% (SOC). The median change in ex time at 3, 6, and 12 months was increased in CD34+ vs. PL (Figure) and angina frequency was decreased (relative risk 0.57 (0.36, 0.92),...
p=0.022) at 6 months.

Conclusion
Premature curtailment of RENEW precluded full assessment of CD34+ therapy. Comparison with both SOC and PL suggests that IM CD34+ therapy improves mortality, ex time, and angina to an extent similar to ACT34 and is a promising therapy for RA patients.

![Graph showing median change from baseline in total exercise time by visit intent-to-treat population as randomized](image)

**Figure 1. Median Change from Baseline in Total Exercise Time by Visit Intent-to-Treat Population as Randomized**

**Other Information**

**Author Disclosures:**

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