High Doses of CD34+ Cells Delivered to Patients in the CardiAMP Cell Therapy (for HF) Trial

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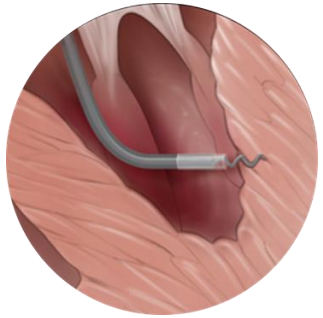
HYPOTHESIS: The estimated retained CD34+ dose provided in this study exceeds that of prior trials evaluating myocardial autologous cell therapy to treat heart failure and myocardial ischemia.

CardiAMP CELL THERAPY TRIAL (NCT02438306)

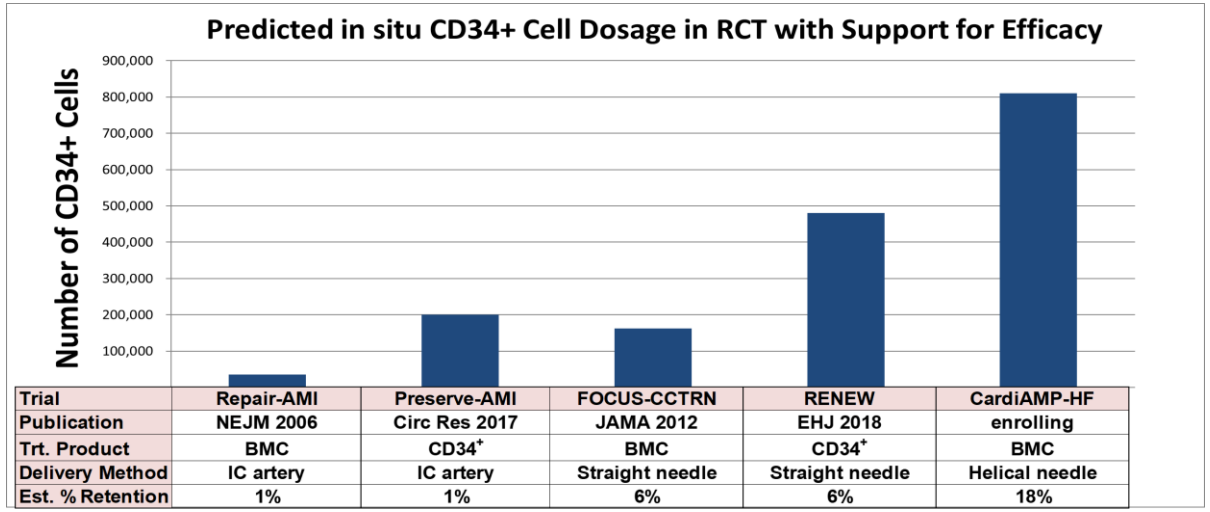
- NYHA Class II / III; ejection fraction 20-40%
- Prescreen patients with a Cell Potency Assay
- Autologous bone marrow cells containing CD34+
- Helical needle delivery with high cell retention
- Transendocardial delivery of concentrated cells

METHODS: Total nucleated cells (TNC) and CD34+ cells from study subject (n=54) bone marrow potency assays were evaluated using flow cytometry (CAGT, Houston, Tx). Predicted in-situ dosages were compared to previous trials having no BMC patient selection and using less efficient cell delivery.



Helical needle-tipped catheter engaged in the myocardium

RESULTS: Mean harvested dose was 627M ± 313 TNC and 4.5M ± 3.4 CD34+ cells, with no significant inter-group or cohort variation. Predicted acutely retained dose is 112M TNC with 810K CD34+ cells.



Trial	Repair-AMI	Preserve-AMI	FOCUS-CCTRN	RENEW	CardiAMP-HF
Publication	NEJM 2006	Circ Res 2017	JAMA 2012	EHJ 2018	enrolling
Trt. Product	BMC	$CD34^+$	BMC	$CD34^+$	BMC
Delivery Method	IC artery	IC artery	Straight needle	Straight needle	Helical needle
Est. % Retention	1%	1%	6%	6%	18%

DISCUSSION: Cell dose compared favorably to the RENEW trial using GCSF mobilized CD34+ products delivered via a straight needle and to the REPAIR AMI trial with CD34+ cells delivered by intravascular infusion.

CONCLUSION: The estimated retained CD34+ dose in this study exceeded that utilized in prior trials. The BMC potency assay used to optimize patient selection, paired with improved local cell retention using the helical needle delivery system, demonstrated higher estimated retained CD34+ dose compared to prior trials of enriched CD34+ cell therapy, suggesting higher likelihood for treatment efficacy than seen previously.

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