

Cardiac Delivery of Autologous Minimally Processed Cell Therapy in HFrEF: Multi-Center, Double-Blind, RCT (CardiAMP HF II)

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OBJECTIVE

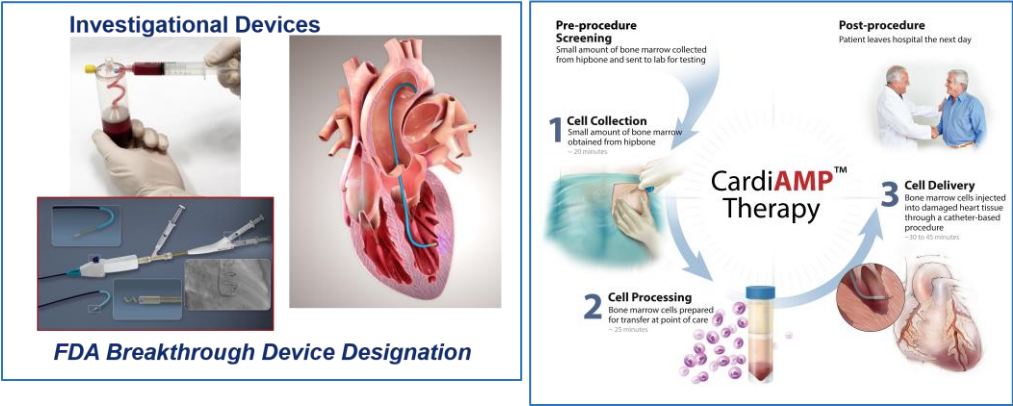
Determine efficacy of high dose autologous bone marrow MNC treatment for patients with ischemic heart failure of reduced ejection fraction (HFrEF) and NTproBNP >500 pg/ml selected for allograft cell characteristics.

POPULATION

- ✓ Chronic ischemic HFrEF, LVEF 20-40%
- ✓ NYHA II/III on max tolerated GDMT
- ✓ NTproBNP >500 pg/ml
- ✓ Flow cytometry-based cell population analysis

STUDY TREATMENT

CardiAMP Cell Therapy. Autologous cells are collected for MNC analysis during screening. On procedure day (Day 0), bone marrow cells are aspirated & processed at the point-of-care (cath lab). Cells are delivered using an intramyocardial injection catheter with a helical-shaped needle designed to increase cell retention.



clinicaltrials.gov: NCT06258447

ACTIVELY ENROLLING -- for additional information about the study scan the QR code:

Trials funded by BioCardia, Inc., Maryland Stem Cell Research Fund (2016-MSCRF-2804) and Centers for Medicare and Medicaid Services (CMS).

Investigational device. Limited by federal (US) law to investigational use only.

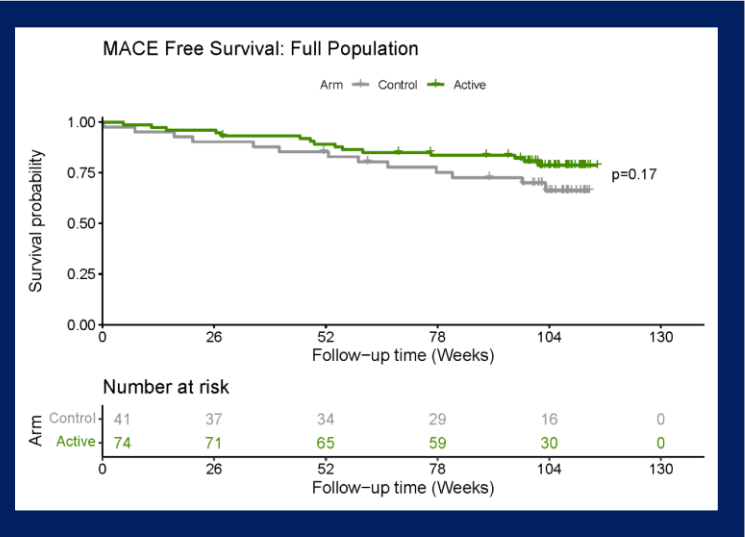
06346-B (MKT)



Previous Results from the CardiAMP HF Trial

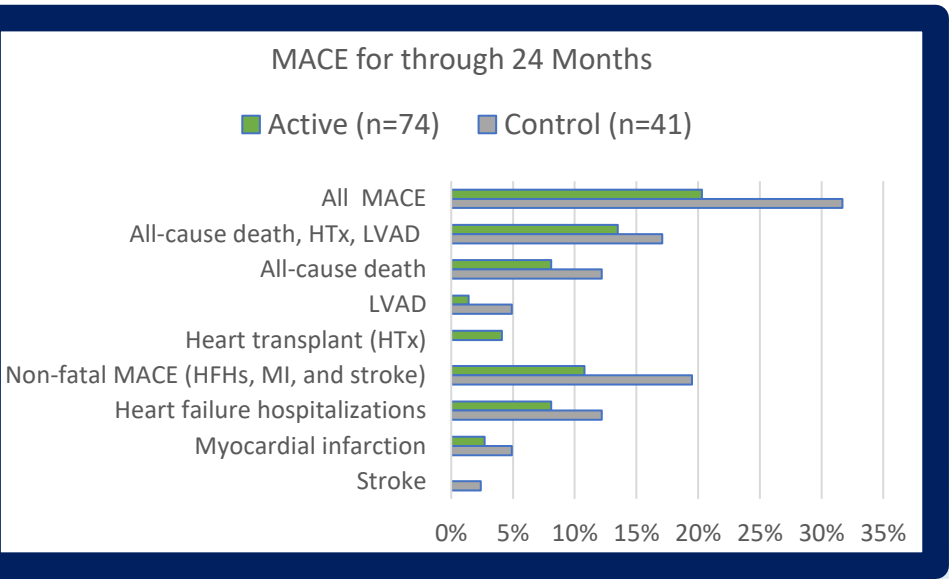
Top-line study results as presented at THT (Technology and Heart Failure Therapeutics), Boston, MA, March 2, 2026.

The recently completed CardiAMP HF Trial (NCT02438306) enrolled 115 patients prospectively selected for screening cell population analysis. Primary outcome was 3-tier composite measure: 1) All cause death, heart transplant, LVAD; 2 Non-fatal MACE (HF hospitalization, MI, stroke); 3) Change in 6MWD from baseline to last follow-up. Other outcomes included quality-of-life questionnaire (MLHFQ; key secondary) and echocardiography. Primary outcome statistically evaluated using Finkelstein-Schoenfeld (F-S) test, Win-Ratio and Kaplan-Meier freedom from MACE.

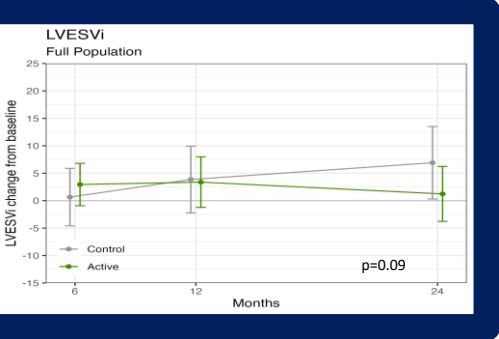


6MWD (M24)
+5.7m +24.1m
F-S p = 0.96
Win Ratio = 0.99
(CI: 0.63, 1.56)

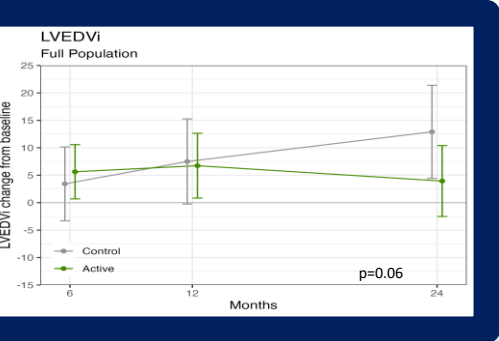
MLHFQ (M24)
-8.6 pts -3.1 pts
F-S p = 0.14
Win Ratio = 1.42
(CI: 0.91, 2.22)



The primary outcome not met due to improvements in 6MWD for both groups. Fewer MACE were seen in treated patients compared to controls. With MLHFQ as tier 3, all 3 tiers favored treatment.



Longitudinal cardiac remodeling as measured by LVESVi and LVEDVi shows continued adverse remodeling through Month 24 for the control group compared to the treatment group.



Forest plot showing outcomes for pre-specified subgroups. Win ratio estimates and 95% confidence intervals for each subgroup are presented as points on the figure for the primary outcome with 6MWD (left) and for MLHFQ (right) as tier 3. Win ratio <1 favors control and win ratio >1 favors treatment; the dashed line represents the win ratio estimate for full population. Favorable treatment effect was seen for women and subgroups of NTproBNP >500 pg/ml and LVEF <32%.

