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STEM CELLS

Myocardial regeneration after infarction—promising phase I trial results

Infusion of cardiosphere-derived stem cells (CDCs) increases the viable heart mass after a myocardial infarction (MI), according to the results of the small, proof-of-concept, phase I CADUCEUS trial. This prospective, randomized study was performed in 25 patients enrolled 2–4 weeks after an MI (mean left ventricular ejection fraction 39%, mean scar size 24% of left ventricular mass) and randomly allocated in a 1:2 ratio to receive either standard care ($n = 8$) or autologous CDCs grown from an endomyocardial biopsy and infused into the infarct-related artery 1.5–3.0 months post-MI ($n = 17$).

No complications were reported after infusion of the CDCs and, after 6 months of follow-up, no patients had experienced the primary safety end point (death, new cardiac tumors, or a major adverse cardiac event). However, more patients in the CDC-treatment group suffered serious adverse events than among controls (24% versus 13%, $P = 1.00$). Preliminary assessment of efficacy end points using MRI indicated that stem-cell treatment was associated with significant reductions in scar mass ($P = 0.001$), and increases in viable heart mass ($P = 0.01$) and regional contractility ($P = 0.02$), but no difference in left ventricular ejection fraction was seen between the groups.

"The unprecedented increases we noted in viable myocardium ... are consistent with therapeutic regeneration," conclude the researchers. "Intracoronary infusion of autologous CDCs after MI is safe, warranting the expansion of such therapy to phase II study."

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Original article Makkar, R. R. *et al.* Intracoronary cardiosphere-dervied cells for heart regeneration after myocardial infarction (CADUCEUS): a prospective, randomised phase 1 trial. *Lancet* doi:10.1016/S0140-6736(12)60195-0