Title
Feasibility of autologous marrow stromal cell therapy in human stroke

Journal
STROKE, 39(2)

ISSN
0039-2499

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Publication Date
2008

was 29 +/- 2 cc. Aspiration was well tolerated, with Visual Analog Pain scores of 2.4 +/- 1.4 (out of 10). Specimen cooler temperatures remained in the target range during round-trip transportation between the marrow donor center and the marrow processing lab. A median of 40 (range 20–225) x 10^6 MNC were available for plating from the marrow. The MSC yield at 21 d was median 2.1 (range, 0.9–4.4) x 10^6 MSC/kg. Median cell viability was 98.5%. All samples were formally cleared for release within the allotted time period, and post-release bacterial and fungal cultures were furthermore negative. Viability of MSC was well maintained in saline at 1 x 10^6 MSC/mL for 24 h at 4 C, but not after 48 h or if stored at room temperature. Subject age correlated with number of marrow nuclear cells ($p<.05$) but not with yield of MSC. CONCLUSIONS: This study suggests the feasibility of a two-hospital, GTP-compliant system for use of autologous MSC to treat subjects with a time-sensitive condition such as subacute stroke. Sufficient MSC that are suitable for human therapy can be rapidly and reliably generated, and the resultant MSC may be preserved for up to 24 h.

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Feasibility of Autologous Marrow Stromal Cell Therapy in Human Stroke.

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INTRODUCTION: Prior studies suggest the potential for autologous marrow stromal cell (MSC) therapy to improve outcome after stroke. The purpose of this study was to evaluate a system to obtain human bone marrow at one institution (UCI), culture MSC at a second institution (UCSD), and returning MSC to the first institution for infusion, under Good Tissues Practice (GTP) conditions. No subjects were treated–this report describes the feasibility of the approach. METHODS: A bone marrow sample was aspirated from the iliac crest of healthy subjects, then transported 82 miles under sterile, temperature-controlled conditions. A mononuclear cell (MNC) fraction was prepared from the marrow, a portion of which was suspended in solution with 20% pre-screened fetal bovine serum and plated in culture flasks. This was maintained at 37 deg C in a 5% CO2 incubator, non-adherent cells were removed at 48 hr, and a portion of the cells were passaged (at 12–14 d, when 80% confluent) into additional flasks. MSC were harvested at 21 d, washed, and resuspended in sterile saline. MSC were identified according to ISCT criteria, including adherence, morphology, growth characteristics, and flow cytometry (+CD73, CD90, CD105; -CD14, CD34, CD45, HLA-DR), plus differentiation into adipocytes. Criteria for releasing specimens from the marrow processing lab to the marrow donor/treatment center included Gram stain, and Mycoplasma and Endotoxin assays. RESULTS: A total of 8 subjects were enrolled, age 56 +/- 22 (mean +/- SD). The marrow volume aspirated