

Adipose-Derived Stromal Vascular Fraction Cells

Duma et al. tested the safety of human intracerebroventricular (ICV) brain injections of autologous non-genetically-modified adipose-derived stromal vascular fraction (ADSVF). In this IRB-approved trial, 24 patients received ICV ADSVF via an implanted [reservoir](#) between 5/22/14 and 5/22/17. Seven others were injected via their [ventriculoperitoneal shunts](#). Ten patients had [Alzheimer's disease](#) (AD), 6 had [amyotrophic lateral sclerosis](#) (ALS), 6 had progressive [multiple sclerosis](#) (MS-P), 6 had Parkinson's "Plus" (PD+), 1 had [spinal cord injury](#), 1 had a [traumatic brain injury](#), and 1 had a [stroke](#). The median age was 74 (range 41-83). Injections were planned every 2-3 months. Thirty-one patients had 113 injections. Patients received SVF injection volumes of 3.5-20 cc (median:4 cc) containing 4.05×10^5 to 6.2×10^7 cells/cc, which contained an average of 8% hematopoietic and 7.5% adipose stem cells. Follow-up ranged from 0 to 36 months (median: 9.2 months). MRIs post-injection(s) were unchanged, except for one AD patient whose hippocampal volume increased from < 5th percentile to 48th percentile (NeuroQuant® volumetric MRI). Of the 10 AD patients, 8 were stable or improved in tests of cognition. Two showed improvement in P-tau and β -amyloid levels. Of the 6 MS-P patients all are stable or improved. Four of 6 ALS patients died of disease progression. Twelve of 111 injections (11%) led to 1-4 days of transient meningismus, and mild temperature elevation, which resolved with acetaminophen and/or dexamethasone. Two (1.8% of injections) required hospitalization for these symptoms. One patient (0.9% of injections) had his reservoir removed and later replaced for presumed infection. In this Phase 1 safety trial, ADSVF was safely injected into the human brain ventricular system in patients with no other treatment options. Secondary endpoints of clinical improvement or stability were particularly promising in the AD and MS-P groups. These results will be submitted for a Phase 2 FDA-approved trial ¹⁾.

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Duma C, Kopyov O, Kopyov A, Berman M, Lander E, Elam M, Arata M, Weiland D, Cannell R, Caraway C, Berman S, Scord K, Stemler L, Chung K, Khoudari S, McRory R, Duma C, Farmer S, Bravo A, Yassa C, Sanathara A, Singh E, Rapaport B. Human intracerebroventricular (ICV) injection of autologous, non-engineered, adipose-derived stromal vascular fraction (ADSVF) for neurodegenerative disorders: results of a 3-year phase 1 study of 113 injections in 31 patients. Mol Biol Rep. 2019 Jul 20. doi: 10.1007/s11033-019-04983-5. [Epub ahead of print] PubMed PMID: 31327120.

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