Young Fresh frozen plasma

Young mouse plasma restores memory in aged mice, but, the effects are unknown in patients with Alzheimer disease (AD).

To assess the safety, tolerability, and feasibility of infusions of young fresh frozen plasma (yFFP) from donors age 18 to 30 years in patients with AD.

The Plasma for Alzheimer Symptom Amelioration (PLASMA) study randomized 9 patients under a double-blind crossover protocol to receive 4 once-weekly infusions of either 1 unit (approximately 250 mL) of yFFP from male donors or 250 mL of saline, followed by a 6-week washout and crossover to 4 once-weekly infusions of an alternate treatment. Patients and informants were masked to treatment and subjective measurements. After an open-label amendment, 9 patients received 4 weekly yFFP infusions only and their subjective measurements were unmasked. Patients were enrolled solely at Stanford University, a tertiary academic medical center, from September 2014 to December 2016, when enrollment reached its target. Eighteen consecutive patients with probable mild to moderate AD dementia, a Mini-Mental State Examination (score of 12 to 24 inclusive), and an age of 50 to 90 years were enrolled. Thirty-one patients were screened and 13 were excluded: 11 failed the inclusion criteria and 2 declined to participate.

One unit of yFFP from male donors/placebo infused once weekly for 4 weeks.

The primary outcomes were the safety, tolerability, and feasibility of 4 weekly yFFP infusions. Safety end point analyses included all patients who received the study drug/placebo.

There was no difference in the age (mean [SD], 74.17 [7.96] years), sex (12 women [67%]), or baseline Mini-Mental State Examination score (mean [SD], 19.39 [3.24]) between the crossover (n = 9) and open-label groups (n = 9). There were no related serious adverse events. One patient discontinued participation because of urticaria and another because of an unrelated stroke. There was no statistically significant difference between the plasma (17 [94.4%]) and placebo (9 [100.0%]) cohorts for other adverse events, which were mild to moderate in severity. The most common adverse events in the plasma group included hypertension (3 [16.7%]), dizziness (2 [11.1%]), sinus bradycardia (3 [16.7%]), headache (3 [16.7%]), and sinus tachycardia (3 [16.7%]). The mean visit adherence (n = 18) was 86% (interquartile range, 87%-100%) and adherence, accounting for a reduction in the total visit requirement due to early patient discontinuation, was 96% (interquartile range, 89%-100%).

The yFFP treatment was safe, well tolerated, and feasible. The study's limitations were the small sample size, short duration, and change in study design. The results warrant further exploration in larger, double-blinded placebo-controlled clinical trials.

TRIAL REGISTRATION: ClinicalTrials.gov Identifier: NCT02256306 [1)].

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Sha SJ, Deutsch GK, Tian L, Richardson K, Coburn M, Gaudioso JL, Marcal T, Solomon E, Boumis A, Bet A, Mennes M, van Oort E, Beckmann CF, Braithwaite SP, Jackson S, Nikolich K, Stephens D, Kerchner GA, Wyss-Coray T. Safety, Tolerability, and Feasibility of Young Plasma Infusion in the Plasma for Alzheimer Symptom Amelioration Study: A Randomized Clinical Trial. JAMA Neurol. 2019 Jan 1;76(1):35-40. doi: 10.1001/jamaneurol.2018.3288. PubMed PMID: 30383097.

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