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Clinical Trial > **Alzheimers Dement.** 2020 Oct;16(10):1412-1425. doi: 10.1002/alz.12137.

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# A randomized, controlled clinical trial of plasma exchange with albumin replacement for Alzheimer's disease: Primary results of the AMBAR Study

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## Abstract

**Introduction:** This phase 2b/3 trial examined the effects of plasma exchange (PE) in patients with mild-to-moderate Alzheimer's disease (AD).

**Methods:** Three hundred forty-seven patients (496 screened) were randomized (1:1:1:1) into three PE treatment arms with different doses of albumin and intravenous immunoglobulin replacement (6-week period of weekly conventional PE followed by a 12-month period of monthly low-volume PE), and placebo (sham).

**Results:** PE-treated patients performed significantly better than placebo for the co-primary endpoints: change from baseline of Alzheimer's Disease Cooperative Study-Activities of Daily Living (ADCS-ADL;  $P = .03$ ; 52% less decline) with a trend for Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog;  $P = .06$ ; 66% less decline) scores at month 14. Moderate-AD patients (baseline Mini-Mental State Examination [MMSE] 18-21) scored better on ADCS-ADL ( $P = .002$ ) and ADAS-Cog ( $P = .05$ ), 61% less decline both. There were no changes in mild-AD patients (MMSE 22-26). PE-treated patients scored better on the Clinical Dementia Rating Sum of Boxes (CDR-sb) ( $P = .002$ ; 71% less decline) and Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC) ( $P < .0001$ ; 100% less decline) scales.

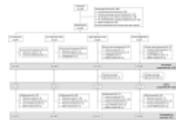
**Discussion:** This trial suggests that PE with albumin replacement could slow cognitive and functional decline in AD, although further studies are warranted.

**Keywords:** Alzheimer's disease; albumin; albutein; clinical trial; plasma exchange; plasmapheresis.

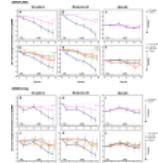
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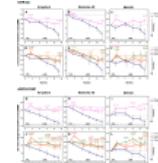
## Figures



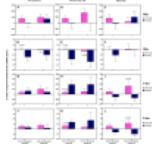
**FIGURE 1** Flowchart of patients through the...



**FIGURE 2** Least square (LS) mean change...



**FIGURE 3** Least square (LS) mean change...



**FIGURE 4** Least square (LS) mean change...

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