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## Lipid and Lipoprotein Metabolism: Clinical V

### Abstract 1501: Do Low Dose Statins Affect Cognition? Results of the UCSD Statin Study

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**Subjects:** 1016 subjects (692 men over age 20 and 324 postmenopausal women), without cardiovascular disease or diabetes, with LDL 115–190mg/dl.

**Design:** Six month double blind RCT with equal allocation to simvastatin 20mg, pravastatin 40mg or placebo; statins chosen for similar lipid reduction at the extremes of lipophilicity.

**Primary endpoints:** Change from baseline for four primary cognitive indices (see Table).

**Analysis:** Primary analysis: T-test of difference in mean comparing statin vs placebo; or regression to adjust for baseline characteristics if baseline disparities between statin and placebo. Secondary analyses stratified effects by sex and statin; and assessed a prespecified hypothesis that mitochondrial vulnerability (using proxies of age and blood pressure) would identify a vulnerable subset.

**Result:** Baseline characteristics were comparable across treatment arms. Mean cholesterol reductions (mg/dl) were  $-2.1 \pm 26$  placebo;  $-57 \pm 29$  simvastatin; and  $-47 \pm 29$  pravastatin. Cognitive variances were high, compatible with broad inclusion criteria. Cognitive endpoints (total sample) showed no significant effect with statins. However stratified analyses suggested possible effect modification, with trends toward harm significant on one-sided analysis for six groups. Additionally, the hypothesis of vulnerable subsets was provisionally supported, with consistent trends toward harm in the mitochondrial subgroup, despite the smaller sample (N=97).

**Conclusion:** Findings provide reassurance that low dose statins confer little average cognitive impact with short term use in a generally healthy population, regardless of lipophilicity. However possible effect modification was provisionally supported. Future studies should evaluate subgroups with potential for differential statin effects; and should assess the higher doses of statins increasingly used in lipid therapy.

Total Sample (N = 1016): Analysis Stratified by Sex and Statin

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Simva: women	NS	NS	NS	
Mitochondrially Vulnerable Subgroup(N=97): Combined statins vsplacebo				
All	Worse*	Worse*	Worse**	
Men	Worse*	Worse	Worse**	
Women	Worse	Worse**	Worse	

\*p < 0.05, one sided. \*\*p < 0.05, two-sided. NS = nonsignificant.

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