Purpose:
Overactive bladder is common in the elderly population, which is susceptible to cognitive disorders and drug-induced cognitive impairment. Existing overactive bladder treatments may cause adverse events, such as cognitive impairment, due to antagonism of the M₁ receptor in the central nervous system. In this study we evaluated the effect of darifenacin, an M₃ selective antagonist, on cognitive function in elderly volunteers without clinical dementia.

Materials and Methods:
This double-blind, 3-period crossover study randomized 129 volunteers 65 years or older with no/mild cognitive impairment to receive 3 of 5 treatments, namely darifenacin controlled release (3.75, 7.5 or 15 mg once daily), darifenacin immediate-release (5 mg 3 times daily) or matching placebo for 14 days. Each treatment period was separated by 7 days of washout. Cognitive function tests were completed at baseline and at treatment end.

Results:
For the primary end points of memory scanning sensitivity, speed of choice reaction time and word recognition sensitivity, there were no statistically significant differences for darifenacin vs placebo. There were no statistically significant differences in secondary variables except memory scanning speed, which increased in all groups relative to baseline, but improvement was greater with placebo than with 3.75 mg darifenacin. Darifenacin treatment was not associated with changes in alertness, contentment or calmness, which are likely to be clinically relevant. Darifenacin was well tolerated.

Conclusions:
In elderly volunteers 2 weeks of treatment with darifenacin had no effect on cognitive function compared with baseline and it was not significantly different from placebo. This may be related to its M₃ receptor selectivity with negligible M₁ receptor antagonism.