Quetiapine and rivastigmine and cognitive decline in Alzheimer’s disease  
BMJ 2005;330:874-10

Study Type: POE  
Purpose: Which drug is better for agitation from dementia - quetiapine or rivastigmine? Does either drug cause cognitive decline?  
Study Duration: 26 weeks  
Patients: 93 patients, mean age 84 years, ~80% female; Baseline scales SIB = 62; CMAI = 59; FAST = 6 (see outcome measures)  
Trial Design: Double-blinded, placebo-controlled, randomized, all people with dementia in living care facilities in Newcastle  
Medications Target: quetiapine 25 - 50 mg BID and Rivastigmine 3 - 6 mg bid  
3 groups - 1) quetiapine + placebo rivastigmine; 2) placebo quetiapine + rivastigmine; 3) both placebo (double dummy)  
Inclusion Criteria: diagnosis of probable AD, age > 60, clinically significant agitation for at least 6 weeks, scores showing irritability and aberrant motor behavior  
Exclusion Criteria: those on antipsychotics or cholinesterase inhibitors for 4 weeks prior to study, severe disability, bradycardia, sick sinus syndrome, PUD  
Outcome Measures: Cohen-Mansfield agitation scale (CMAI); Severe Impairment Battery for agitation (SIB) - 40 item test to evaluate cognitive dysfunction (memory, orientation, language, attention, praxis, social interaction, orientation to name); scores range from 0 to 100, higher scores reflect higher levels of cognition; FAST (Functional Assessment Staging) - assesses ability to perform daily life activities.

1. Are the results valid?  
   * randomized? Yes  
   * double-blinded? Yes  
   * placebo-controlled? Yes  
   * were study groups similar? yes  
   * all patients accounted for? Yes  
   * allocation concealment? Yes

2. What were the results?  
   * no significant difference in change in agitation inventory scores (CMAI) between baseline and 26 weeks.  
   * SIB - those patients on quetiapine had a significantly greater deterioration in cognitive functioning at 6 weeks (p = .009) and at 26 weeks (p = .01). There was no deterioration in the rivastigmine group as compared to placebo.  
   * FAST data was not reported

3. Will the results help me?  
   * those with poor cognitive functioning were likely to drop out of the study  
   * no adverse events reported

Conclusion: Quetiapine does not result in significant improvement in agitation in patients with dementia and is associated with a greater decline in cognitive functioning. Patients in the rivastigmine group did not experience any improvement in agitation nor did they seem to experience a decline in cognition as compared to placebo.