Galantamine in AD: a 6-month randomized, placebo-controlled trial with a 6-month extension
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Study Type: POEM
Purpose: To evaluate the safety and efficacy of 24 and 32 mg/d of galantamine in patients with mild to moderate AD.
Study Duration: 6 month trial with an open-label for an additional 6 months
Patients: 636 patients, mean age ~76, ~60:40 female: male, ~92% white, MMSE = ~19, ~67 kg, ADAS-cog baseline = 25, DAD score = 71, most were diagnoses 1 to 1.5 years
Trial Design: randomized, double-blinded, placebo-controlled, multicenter (33 sites); placebo vs 24 mg/d vs 32 mg/d galantamine, doses were begun at 8 mg/day and increased weekly to desired dose, all daily doses were given bid
Inclusion: cognitive decline that had been gradual in onset but progressive over at least 6 months; diagnosis of probable AD; MMSE score of 11-2; > than 12 on ADAS-cog; reliable caregiver
Exclusion: hypertension; CHF; noninsulin dependent DM, any endocrine disorder, bad stroke; CV disease with poor prognosis; those with seizures, renal, hepatic disorders, pulmonary, drug or alcohol abuse, etc - lots of exclusion criteria
Outcome Scores: ADAS-Cog - on average, those with moderate AD will have a 7-11 point increase in ADAS-Cog (cognitive decline) CIBIC - likert scale, 1 = marked improvement, 4 = no change, 7 = marked worsening
Secondary Scores: ADL's assessed by Disability Assessment for Dementia Scale (DAD scale) - 46 questions, scores range from 0 to 100

1. Are the results valid?
   * randomized? yes
   * double-blinded? yes
   * were groups similar? yes, except for age in 10 mg group, 2 years older
   * all patients accounted for? yes

2. What were the results
   ADAS-cog scores improved over baseline within 1 week of reaching a galantamine dose of 24 mg per day. At 6 months, scores improved by 1.7 points using either dose of galantamine verses placebo. Placebo declined by 2.2 points (p < .001). Extending the drug an additional 6 months shows maintenance of cognitive function relative to baseline.

   CIBIC-plus - 70% on either dose of galantamine improved over 6 months compared with 55% on placebo. No real difference between the CIBIC-plus in any of the treatment groups, including placebo in the extension portion of the study. Response was 54 to 61%.

   DAD scale - there was no statistical significant difference between the galantamine groups for this score from baseline at 6 or 12 months. There was decline in the placebo group at 12 months.

3. Will the results help me?
   * difficult to apply the results of this trial to patients
   * like donepezil no change over time might be beneficial
   * for every 4 patients treated, one will get nausea and one out of 7 will discontinue the drug due to side effects
   * Point differences between drug- and placebo-treated patients on quantitative scales do not necessarily indicate that these effects are clinically relevant.
   * Galantamine (Reminyl®) cost $140.00 for a month supply of 12 mg bid.