

**PW01-66 - DOES ATOMOXETINE IMPROVE EXECUTIVE FUNCTION AND INHIBITORY CONTROL AS MEASURED BY AN OBJECTIVE COMPUTER-BASED TEST? A RANDOMIZED, PLACEBO-CONTROLLED STUDY**

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**Objectives:** Primary objective was to evaluate the influence of atomoxetine on standard variables of a computer-based Continuous Performance Test (cb-CPT) that reflects executive function and inhibitory control in children with ADHD.

**Methods:** Two-arm, 8-week, placebo-controlled, randomized, double-blind study in ADHD patients (6-12yrs). Atomoxetine was initiated at 0.5 mg/kg qd for 1 week, followed by 7 weeks on the target dose of 1.2 mg/kg qd. Primary outcome were the q-scores of the cb-CPT standard variables after 8 weeks using mixed models for repeated measurement. Additionally, ADHD-RS scores, WREMB (Weekly Ratings of Evening and Morning Behavior) and CGI-S-ADHD were assessed (weeks 0,1,2,4,6,8).

**Results:** N=128 patients were randomized, N=125 evaluated (atomoxetine/placebo: 63/62). Baseline characteristics were comparable (77.6% boys; 40.0% patients with ODD/CD; 24.8% prior stimulant treatment; mean ( $\pm$ SD) age 9.0 $\pm$ 1.79yrs; mean ADHD-RS total score 36.99 $\pm$ 11.56). At Week 8, all primary outcomes (cb-CPT q-scores) were significantly reduced vs. placebo (all  $p < 0.001$ ) for mean (effect size [ES] 0.41), variance (ES=0.71), and normalized variance (ES=0.50) of "Reaction time", "Number of microevents" (ES=1.00), "Commission errors" (ES=0.50), "Omission errors" (ES=0.70), "Distance of movement" (ES=0.90) and "Area of movement" (ES=1.08), "Time active" (ES=0.69), and "Motion simplicity" (ES=0.38). Secondary endpoints at Week 8 improved significantly in favor of atomoxetine: ADHD-RS: total score ES=1.30,  $p < 0.001$ ; hyperactive/impulsive subscore ES=1.37,  $p < 0.001$ ; inattentive subscore ES=1.07,  $p < 0.001$ ). WREMB: total score ES=1.00,  $p < 0.001$ ; morning subscore ES=0.59,  $p=0.002$ ; evening subscore ES=1.02,  $p < 0.001$ . CGI-S-ADHD: ES=1.11;  $p < 0.001$ .

**Conclusions:** Atomoxetine for 8 weeks significantly reduced ADHD symptoms as measured by the objective cb-CPT.