Preschool ADHD Treatment Study (PATS),

PATS was a National Institutes of Mental Health-funded, multicenter, randomized, efficacy trial designed to evaluate the short-term (5 weeks) efficacy and long-term (40 weeks) safety of methylphenidate (MPH) in preschoolers with attention-deficit/hyperactivity disorder (ADHD). The PATS study involved 303 children (age range, 3–5.5 years) who met DSM-IV criteria for combined-type ADHD.

All the children were initially enrolled in an intensive 10-week behavioral therapy program which included parent counseling. The outcome of the behavioral therapy phase was that there was a significant reduction of ADHD symptoms in one third of the children and they did not need to advance to the medication phase of the study.

Approximately two thirds of the remaining children whose behaviors had not improved after behavioral therapy and whose parents agreed to a medication trial entered a 5-week, placebo-controlled, double-blind trial in which 165 children were randomized to receive placebo or 1.25 mg, 2.5 mg, 5.0 mg, or 7.5 mg of immediate-release methylphenidate (MPH) three times daily. Outcomes were measured with standardized ADHD questionnaires completed by parents and teachers. Compared with controls, children who received the 2.5 mg, 5.0 mg, and 7.5 mg doses of MPH had significant reductions in ADHD symptoms. The mean effective total daily dose of MPH was 14.2 (+/−8.1) mg/day.

After the controlled phase, 140 children entered a 10-month open-label maintenance trial. By the end of the maintenance phase, the mean effective total daily dose of MPH rose from 14.2 mg/day to 20.5 mg/day. Thirty percent of parents reported moderate-to-severe adverse effects which included emotional outbursts, difficulty falling asleep, repetitive behaviors and thoughts, loss of appetite and irritability. Eleven percent of children in this phase discontinued MPH. Among the 95 children who remained on MPH, annual growth rates were 20% lower than expected for height (−1.38 cm/year) and 55% lower for weight (−1.32 kg/year).

Findings from the PATS Study

1. Preschoolers are likely to have more adverse effects on regular doses of MPH than older children. Using low dose methylphenidate (for example, Ritalin) to treat children age 3–5 years diagnosed with severe ADHD however can be effective.
2. ADHD sometimes has co-existing disorders such as anxiety and oppositional defiant disorder and learning disabilities. The study found that a preschooler’s response to medication was associated with the number of coexisting mental disorders the child has. Children with fewer coexisting disorders were most likely to respond to methylphenidate treatment, whereas those with three or more coexisting disorders did not respond to the treatment.
3. A significant finding was that one third of these children did not need to advance to the medication phase of the study because the 10-week behavioral therapy program for the children and parents effectively reduced their ADHD symptoms. Early behavioral interventions designed to reduce symptoms of ADHD in preschoolers is therefore recommended as an alternative first line of treatment or an effective addition to medication treatment.

References:

Scott, Kollins, Swanson, James, Rationale, design, and methods of the preschool ADHD Treatment Study (PATS), Journal of American Academy of Child and Adolescent Psychiatry, 2006