Journal of the American Academy of Child & Adolescent Psychiatry

Volume 45, Issue 11, November 2006, Pages 1284-1293

SPECIAL SECTION: PRESCHOOL ADHD TREATMENT STUDY-PATS

Efficacy and Safety of Immediate-Release Methylphenidate Treatment for Preschoolers With ADHD

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https://doi.org/10.1097/01.chi.0000235077.32661.61

ABSTRACT

Objective

The Preschool ADHD Treatment Study (PATS) was a NIMH-funded, six-center, randomized, controlled trial to determine the efficacy and safety of immediate-release methylphenidate (MPH-IR), given t.i.d. to children ages 3 to 5.5 years with attention-deficit/hyperactivity disorder (ADHD).

Method

The 8-phase, 70-week PATS protocol included two double-blind, controlled phases, a crossover-titration trial followed by a placebo-controlled parallel trial. The crossover-

titration phase's primary efficacy measure was a combined score from the Swanson, Kotkin, Atkins, M-Flynn, and Pelham (SKAMP) plus the Conners, Loney, and Milich (CLAM) rating scales; the parallel phase's primary outcome measure was excellent response, based on composite scores on the Swanson, Nolan, and Pelham (SNAP) rating scale.

Results

Of 303 preschoolers enrolled, 165 were randomized into the titration trial. Compared with placebo, significant decreases in ADHD symptoms were found on MPH at 2.5 mg ($p < .01$), 5 mg ($p < .001$), and 7.5 mg ($p < .001$) t.i.d. doses, but not for 1.25 mg ($p < .06$). The mean optimal MPH total daily dose for the entire group was 14.2 Â± 8.1 mg/day (0.7 Â± 0.4 mg/kg/day). For the preschoolers ($n = 114$) later randomized into the parallel phase, only 21% on best-dose MPH and 13% on placebo achieved MTA-defined categorical criterion for remission set for school-age children with ADHD.

Conclusions

MPH-IR, delivered in 2.5-, 5-, and 7.5-mg doses t.i.d., produced significant reductions on ADHD symptom scales in preschoolers compared to placebo, although effect sizes (0.4-0.8) were smaller than those cited for school-age children on the same medication.
J. Am. Acad. Child Adolesc. Psychiatry, 2006;45(11):1284-1293.

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Key Words:

preschool; attention-deficit/hyperactivity disorder; psychopharmacology; treatment; adverse events

This research was supported by a cooperative agreement between the National Institute of Mental Health and the following institutions: University of California, Irvine (U01 MH60833), Duke University Medical Center (U01 MH60848), NYSPI/Columbia University (U01 MH60903), New York University Child Study Center (U01 MH60943), University of California, Los Angeles (U01 MH60900), and Johns Hopkins University (U01 MH60642).

The opinions and assertions contained in this report are the private view of the authors and are not to be construed as official or as reflecting the views of the National Institute of Mental Health, the National Institutes of Health, or the Department of Health and Human Services.

Disclosure: The authors' relationships with for-profit enterprises for the period 2000-2006 are as follows: Dr. Kollins: Cephalon, Pfizer, Psychogenics, Shire, Eli Lilly, New River Pharmaceuticals, McNeil; Dr. Greenhill: Eli Lilly, Shire Pharmaceuticals, Cephalon, McNeil, Celltech, Novartis, Sanofi Aventis, Otsuka, Janssen; Dr. Swanson: Cephalon, Eli Lilly, Janssen, McNeil, Novartis, Shire, UCB; Dr. S. Wigal: McNeil, Cephalon, Shire, Eli Lilly; Dr. Abikoff: McNeil, Shire, Eli Lilly, Pfizer, Celltech, Novartis; Dr. McCracken: Eli Lilly, Wyeth, Shire, Pfizer, McNeil, Novartis, Bristol-Myers Squibb, Janssen; Dr. Riddle: Pfizer; Dr. McGough: Eli Lilly, McNeil, Novartis, Shire, Pfizer, New River Pharmaceuticals; Dr. Posner: GlaxoSmithKline, Forest Laboratories, Eisai Inc., AstraZeneca Pharmaceuticals, Johnson & Johnson, Abbott Laboratories, Wyeth Research, Organon USA, Bristol-Myers Squibb, Sanofi-Aventis, Cepalon, Novartis, Shire Pharmaceuticals, and UCB Pharma; Dr. T. Wigal: Cephalon, Eli Lilly, McNeil, Shire; Mr. Davies: Pfizer, Amgen, Johnson & Johnson, Wyeth, Merck, GlaxoSmithKline, Bard. Dr. Cunningham receives compensation for talks and workshops regarding the COPE program. The other authors have no financial relationships to disclose.

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