Effects of risperidone in children with autism

Crystal Branch

ANOVA Article Critique

Researchers complied detailed data regarding two groups a sample group and a controlled group of children to study the cognitive effects of risperidone in children with autism and irritable behavior. The study employed specific measurements designed to determine if children with autism and irritable behavior have an increase of cognitive performance while taking up to 3. 5 mg of risperidone. Recently a few studies have assessed cognitive effects of risperidone in children with severe behavioral disturbance. Günther et al. (2006) assessed open-label risperidone in 23 children with attention-deficit/hyperactivity disorder (ADHD) and disruptive behavior disorders (DBDs) and in normal controls matched for age and IQ.

This was a multi-site investigation that was conducted at five medical centers. After being assessed at the screen visit, participants who met inclusion criteria for the study were then reassessed with clinical instruments at baseline and weekly for the next 8 weeks. So, researchers decided to conduct a double-blind placebo controlled groups on their attention span, how well their verbal learning skills are, diminished or improved hand/eye coordination, and spatial memory was evaluated. Each of the areas was measured before, during and after 8 weeks of participation. All changes in performance were compared by repeated measures ANOVA.

Will the use of risperidone in doses 0. 5 up to 3. 5 mg/day researchers want to know the question what the overall effect the drug has the on cognitive performance of children ages of 5-17 years old, diagnosed with autism and

that suffer from irritable behavior. The review will show what was used to assess the variables and statistical methods created to decide if the study produced any valid result. The authors want to know answers through research if there are actually any significant effects the drug actually has on cognitive processing abilities in autistic children that also suffer from irritable behavior that uses risperidone. Through research and study, the authors looked for answers to this question and set a hypothesis they created around their research study. The authors implied that the null hypothesis (Ho) is that there would be no difference between placebo and risperidone (Aman, M. G., Hollway, J. A., McDougle, C. J., Scahill, L., Tierney, E., McCracken, J. T., . . . Posey, D. J. (2008).

The alternative hypothesis (*H a*) should indicate that there would be a difference between cognitive performance of the sample group vs the controlled group. A total of 38 children between the ages of 5-17 years of age were a part of the sample group, these children have been diagnosed with autism and severe behavior disturbance.

Any participants receiving psychotropic medicines before the study went through a washout for at least 2 weeks prior to randomization (4 weeks for antipsychotics or fluoxetine). Cognitive assessments were done at Baseline, Week 4 and Week 8. Participants were started at either 0. 25 or 0. 50 mg with gradual adjustments over the first four weeks. Maximum dose for smaller subjects (15-45 kg) was 2. 5 mg/day, whereas the maximum dose for larger participants (45 kg.) could be as high as 3. 5 mg/day (1).

As protocol requires during this period as in any clinical study, the subjects did not receive any form of their usual treatment so the effects of any current treatments are eliminated or assumed to be eliminated from their system for the benefit of this study. Instead of immediately stopping and starting any new treatment, there will be a 2-4week time period where the treatment from the first drug is washed out of the patient’s system.

Study participants were male and female children or adolescents, ages 5 to 17 years 2 months, with mental ages 18 months who had autism and severe behavioral disturbance. To be enrolled in the study, participants received a score of 18 on the Irritability subscale of the Aberrant Behavior Checklist (ABC) (Aman and Singh 1994). In addition, participants must have been rated with a Clinical Global Impressions-Severity (CGI-S) score of 4 by an experienced clinician (CGI-S; NIMH 1985, Arnold et al. 2000), and according to the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) (American Psychiatric Association, 1994) a lifetime diagnosis of autistic disorder. The diagnosis of autism was based on a clinical evaluation that included a DSM-IV interview with a parent and direct observation of the participants. The clinical diagnosis was corroborated by structured interview with one or more parents acting as informants, using the Autism Diagnostic Interview-Revised (Lord et al. 1994).

This study has several limitations that caution against over-embracing the statistically-significant (and one equivocal) findings. First, given the exploratory nature of this work (there is only one other study of atypical antipsychotics in children with PDDs), we adopted the . 05 level for alpha. Had we corrected for multiple comparisons, none of the comparisons would

have exceeded alpha. Second, only a minority of our participants were able to perform these tasks. This resulted in (a) small sample sizes and (b) the observation that the testable group had a higher IQ and was older than the untestable group.

Despite these obvious limitations, the findings are noteworthy for several reasons. First, autistic disorder is often coupled with a substantial cognitive disability. Secondly, the significant diversification, indicated by partial eta squared, indicates substantial gains in adaptive skills if upheld by future studies. Next, it is noteworthy to point out that data assembled from various sites under double-blind conditions, which may help to dismiss any individual examiner effects. Finally, the mechanism of any improvement is unknown.