10-2015

Effects of Sertraline Treatment for Young Children with FXS

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**Recommended Citation**

Ligsay, Andrew; Hess, Laura Greiss; Fitzpatrick, Sarah; Lemons Chitwood, Kerrie; Polussa, Jonathan; Siyahian, Salpi; and Hagerman, Randi, "Effects of Sertraline Treatment for Young Children with FXS" (2015). *Collected Faculty and Staff Scholarship*. 111.  
https://scholar.dominican.edu/all-faculty/111

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INTRODUCTION AND PURPOSE
Selective serotonin reuptake inhibitors (SSRIs) help treat many of the phenotypic manifestations of fragile X syndrome (FXS) including anxiety, sensory processing challenges, and communication and intellectual deficits. However, the efficacy of SSRIs has not been previously studied in children with FXS under five-years-old. The purpose of this study was to elucidate group differences in behavior and developmental outcome measures for young children with FXS when treated with sertraline compared to placebo.

PARTICIPANTS and DESIGN
- 57 participants with FXS, ages 2 – 6 years old (mean 3.9 years; SD 1.1)
- Randomized, 6-month, double-blind, placebo-controlled trial of sertraline (Zoloft)
- Baseline and post-treatment outcomes measured
- Primary outcomes: Mullen Scales of Early Learning (MSEL) express language subscales and Clinical Global Impression Scale-Improvement (CGI-I)
- Secondary outcomes: MSEL fine motor, visual perception, and receptive language subscales; Autism Diagnostic Observation Schedule, Second Ed (ADOS-2); Visual Analog Scale (VAS); Sensory Processing Measure-Preschool (SPM-P); and Preschool Language Scale, Fifth Ed. (PLS-5)

RESULTS

Consolidated Standards of Reporting Trials (CONSORT) flow diagram

Primary Outcome Results

<table>
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<th>Variable</th>
<th>Baseline</th>
<th>Follow Up</th>
<th>Baseline</th>
<th>Follow Up</th>
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<td>MSEL</td>
<td>N Mean</td>
<td>SD</td>
<td>N Mean</td>
<td>SD</td>
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<tr>
<td>CGI-I</td>
<td>20 21.3  11.3</td>
<td>13.8 6.6</td>
<td>20 21.3  11.3</td>
<td>13.8 6.6</td>
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<td>13.8 6.6</td>
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<td>VAS</td>
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<td>10.5 4.5</td>
<td>20 80.77</td>
<td>10.5 4.5</td>
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<tr>
<td>ADOS-2</td>
<td>20 34.03</td>
<td>9.3 2.8</td>
<td>20 34.03</td>
<td>9.3 2.8</td>
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Comparison of Adverse Events

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<th>No. of Patients</th>
<th>No. of Patients</th>
<th>P value</th>
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<td>15 51.72</td>
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<td>Any Moderate/Severe AE</td>
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<td>Drug Related</td>
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<tr>
<td>No drug related AE</td>
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<td>6 20.60</td>
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<td>21 80.77</td>
<td>23 79.31</td>
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REFERENCES

CONCLUSIONS
• This is the first known controlled trial of sertraline in young children with FXS.
• No significant differences were observed in the MSEL express language subscales and CGI-I primary outcome measures for sertraline when compared to placebo.
• Secondary measures revealed significant social improvement in the SPM-P. Areas of fine motor and visual perception were also significantly improved on the MSEL when compared to age equivalent subjects. Post hoc analysis combining all MSEL age-equivalent scores (expressive, visual, receptive and fine motor) showed overall significant improvement.
• Results suggest sertraline had significant positive effect on social improvements and overall development.
• Adverse events (AEs) were similar between sertraline and placebo groups. No significant differences in characteristics of AEs were observed between both groups.

SELECTED REFERENCES

ACKNOWLEDGMENTS and CONTACT
• This study was funded by Health Resources and Services Administration (HRSA, H84AMC22641).
• Our sincerest thanks to the FXS families who participated in this study and to the FXS community for supporting this research.
• MIND Institute Sertraline Team: Lauren Bishop, Tasleen Chechi, Susan Harris, Andrea Schneider, Kylie Cokk, Beth Goodlin-Jones, David Hessl, Pam Gallego, Louise Gane, Michele Ono and Julie Morello.
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