Effects of Sertraline Treatment for Young Children with FXS

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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) expressive language subscales and Clinical Global Impression Scale-Improvement (CGI-I)
- Secondary outcomes: MSEL fine motor, visual reception, and receptive language subscales; Autism Observation Diagnostic Schedule, Second Edition (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

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Distribution of Clinical Global Impression-Improvement (CGI-I) scores.

Effect Sizes of Sertraline on Mullen Scales of Early Learning Secondary Measures

Effect Sizes of Sertraline on Sensory Processing Measure – Preschool (SPM-P)

Comparison of Adverse Events

CONCLUSIONS
- This is the first known controlled trial of sertraline in young children with FXS.
- No significant differences were observed in the MSEL expressive 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

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- MIND Institute Sertraline Team: Lauren Bishop, Tasleem Chechi, Susan Harris, Andrea Schneider, Kylee Cook, Beth Goodlin-Jones, David Hessl, Pam Gallego, Louise Gane, Michele Ono and Julie Morcillo.
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