

Trigeminal Nerve Stimulation for Children With Prenatal Alcohol Exposure

NCT06847165

Status	RECRUITING
Phase	Not Applicable
Sponsor	University of California, Los Angeles
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (8)

- Fetal alcohol syndrome, partial fetal alcohol syndrome, or alcohol-related neurodevelopmental disorder per modified Institute of Medicine criteria (thus positive maternal drinking in pregnancy required, facial stigmata not required)
- Prenatal alcohol exposure (PAE) ≥ 6 drinks/week for ≥ 2 weeks and/or ≥ 3 drinks on ≥ 2 occasions throughout gestation per Health Interview for Women/Health Interview for Adoptive and Foster Parents (HIW/HIAFP)
- Diagnosis of Diagnostic and Statistical Manual 5th edition (DSM-5) attention deficit hyperactivity disorder (ADHD), including problems with inattention, hyperactivity, impulsivity, and/or executive function. Screening for ADHD will be done using the Swanson, Nolan, and Pelham Teacher and Parent Rating Scale (SNAP IV). Formal diagnosis of ADHD will be based on the Mini-International Neuropsychiatric Interview for Children and Adolescents (MINI-KID) with input from the Behavior Rating of Executive Function (BRIEF II) and the Conners 4.
- Parent and child able to complete testing in English
- Child able to cooperate during MRI
- ... and 3 more (see full listing online)

Exclusion (7)

- Other toxic exposure per HIW/HIAFP whose influence clearly surpasses that of alcohol (very rare) per study clinician judgement
- Known genetic syndrome associated with ADHD-like symptoms including fragile X, tuberous sclerosis, or generalized resistance to thyroid hormone
- Serious medical or neurologic illness likely to influence brain function, e.g., seizures, closed-head trauma
- Gestation < 34 weeks
- Ferromagnetic metal, claustrophobia, or other MRI or TNS contraindication (e.g., insulin pumps or other body-worn devices)
- ... and 2 more (see full listing online)

Locations (1 total)

University of California Los Angeles Semel Institute Division of Child & Adolescent Psychiatry, Los Angeles, California, United States

<https://clinicaltrials.gov/study/NCT06847165>

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