

Early Treatment of Language Impairment in Young Children With Autism Spectrum Disorder With Leucovorin Calcium

NCT04060017

Status	RECRUITING
Phase	Phase 2
Sponsor	Southwest Autism Research & Resource Center
Enrollment	80 participants

Key Eligibility Criteria

Inclusion (7)

- Autism Spectrum Disorder (as defined below).
- Between 2 years 6 months and 5 years 2 months of age at baseline
- Language impairment (Ages and Stage Questionnaire between -1 and -3 SD for Language)
- Has at least 4 month old expressive language ability as assessed by the MSEL Expressive Language Scale (i.e., Parent answers "yes" to " Voluntary babbling (such as 'bu, bu, bu)")" Question #7 on the MSEL Expressive Language Scale.
- English included in the languages in which the child is being raised
- ... and 2 more (see full listing online)

Exclusion (17)

- Known FRAA status by clinically validated test performed outside of research studies.
- Mineral or vitamin supplementation that exceeds the Tolerable Upper Daily Intake Levels set by the Institute of Medicine (See Table 5 below)
- Significant self-abusive or violent behavior or evidence of suicidal ideation, plan or behavior
- Severely affected as defined by CGI-Severity Standard Score = 7 (Extremely III)
- Severe prematurity (<34 weeks gestation) as determined by medical history
- ... and 12 more (see full listing online)

Locations (2 total)

Southwestern Autism Research & Resource Center, Phoenix, Arizona, United States
State University of New York, Downstate, Brooklyn, New York, United States