

# Treatment of Social and Language Deficits With Leucovorin for Young Children With Autism

NCT04060030

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

## Key Eligibility Criteria

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### Inclusion (10)

- \. Autism Spectrum Disorder (diagnosed as Autistic Disorder on the ADOS-2 or the ADI-R).
- Between 2 years 6 months and 5 years 2 months of age at baseline
- Folate Receptor Alpha Autoantibody Positive status
- Language impairment (Ages and Stage Questionnaire between -1 and -3 SD for Language)
- English included in the languages in which the child is being raised

... and 5 more (see full listing online)

### Exclusion (21)

- 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 6 below)
- Significant self-abusive or violent behavior or evidence of suicidal ideation, plan or behavior
- Severely affected children as defined by CGI-Severity Standard Score = 7 (Extremely III)
- Severe prematurity (<34 weeks gestation) as determined by medical history

... and 16 more (see full listing online)

## Locations (2 total)

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