

Treating Young Children With Attention Deficit Hyperactivity Disorder

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 3 years to 5 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. Males or females 3 to 5 years of age, inclusive (e.g. children age 5 years, 11 months are eligible).
2. Child has a confirmed diagnosis of moderate or severe Attention-Deficit/Hyperactivity Disorder (diagnostic code: F90.9) based on Diagnostic and Statistical Manual of Mental Disorders - 5th Edition (DSM-5) criteria, review of supportive evidence (caregiver interview, behavioral observations, Vanderbilt Attention-Deficit/Hyperactivity Disorder Rating Scale results, any school or daycare information provided by caregiver).
3. Clinician-rated Clinical Global Impairment-Severity (see description below) rating of ≥ 4 (denoting moderate or greater impairment due to their Attention-Deficit/Hyperactivity Disorder symptoms).
4. The child's clinician and caretakers have decided on or are considering initiating drug therapy (with either Methylphenidate or Guanfacine).
5. Primary language is English or Spanish.

Exclusion Criteria:

1. History of taking Methylphenidate or Guanfacine. Prior use of other Attention-Deficit/Hyperactivity Disorder medications or other psychotropic medications is allowed.
2. Current use of other Attention-Deficit/Hyperactivity Disorder medications (e.g., amphetamines), other psychotropic medications (e.g., atypical antipsychotics or serotonin reuptake inhibitors), or centrally active depressants (such as phenothiazines, barbiturates, or benzodiazepines)
3. Electronic Health Record documentation of moderate to severe global developmental delay (F88) or intellectual disability (F70), or a score of < 55 on the Vineland Adaptive Behavior Scales-3.
4. Medical contraindications to taking Methylphenidate or Guanfacine, including cardiac risk factors (e.g. known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmias, coronary artery disease, or other serious cardiac disease), increased intraocular pressure, glaucoma, verbal tics, Tourette's Syndrome, psychosis

Conditions & Interventions

Interventions:

DRUG: Guanfacine (GUA), DRUG: Methylphenidate (MPH)

Conditions:

Attention-Deficit/Hyperactivity Disorder (ADHD)

Keywords:

Attention-Deficit/Hyperactivity Disorder, Methylphenidate, Guanfacine, Preschool Children, Comparative Effectiveness, Prospective Study

More Information

Description:

This project will evaluate the effectiveness of Methylphenidate versus Guanfacine in treating Attention-Deficit/Hyperactivity Disorder (ADHD) in children aged 3 through 5 years (inclusive), as measured by clinician rating of global improvement.

Contact(s): Hannah Bush, MA - ddbp.adhd.research@cchmc.org

Principal Investigator:

Principal Investigator ID:

Phase: PHASE4

IRB Number:

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