# AWARE: Management of ADHD in Autism Spectrum Disorder

Status: RECRUITING

## Eligibility Criteria

Sex: ALL
Age: 4 years to 17 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Participant and/or legal caregiver must be willing and able to give informed consent/assent for participation in this study.
2. Participant and/or legal caregiver must be willing and able (in the Investigator's opinion) to comply with all study requirements.
3. Participant must be between 4 and 17 years of age (inclusive) at time of enrollment.
4. Participant must have a confirmed diagnosis of ASD based on supportive evidence (e.g. referring physician's report, medical records, such as ADOS or CARS, etc.).
5. Participant must have the ability to consistently take medication (via pill, liquid or mixed with food/liquid).
6. Participant must have a confirmed diagnosis of ADHD (based upon DSM-5 criteria and supportive evidence).
7. Participant must have a consistent reporter (e.g., parent) who spends regular time with the child.
8. Participant can be on other psychotropic medications (selective serotonin reuptake inhibitor (SSRI), atypical antipsychotic, anticonvulsant) if dose has been stable for > 4 weeks prior to consent with no plans for a dose change during the study.
9. It has been at least 7 days since the participant last took an ADHD medication and the presiding clinician believes this to be a sufficient amount of time.
10. Caregiver must be sufficiently fluent in English or Spanish to be able to complete questionnaires relevant to this study.

Exclusion Criteria:

1. Participant has taken ADHD medication within the past 7 days.
2. Participant is not stable on other medications (< 4 weeks).
3. Any other risk factor that might prevent patient from safely taking the study medications.

- There are no inclusion/exclusion criteria based upon participant IQ. We will include individuals across the entire range of cognition, just as practitioners are asked to treat ADHD in children with ASD across the entire IQ range.

## Conditions & Interventions

Interventions:
DRUG: Randomization to either Amphetamine (AMP) class of stimulant medication or Methylphenidate (MPH) class of stimulant medication, DRUG: Randomization to either Alpha 2 agonist class of medication or alternate class of stimulant.
Conditions:
ADHD, Autism Spectrum Disorder
Keywords:
ADHD, Autism, ASD

## More Information

Description:
This study is a pragmatic clinical trial examining the comparative effectiveness of two stimulant medications (methylphenidate and amphetamine) in the treatment of ADHD in children and adolescents with autism. Using a sequential, multiple assignment randomization trial (SMART) design the study will not only assess these two medications but also the role of an increasingly popular class of ADHD medication, the alpha-2 agonists. Findings from this study will help improve clinicians' approach to medication selection and reduce the repeated trials of multiple medications that are current standard care.

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