

# Medication Study for ASD

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**NIH Autism Center  
of Excellence**

## Frequently Asked Questions

### **1. What does the medication do and why do you think it will help people with autism spectrum disorder (ASD)?**

The medication in the study is called AZD7325. New drugs have simple names like this early in their development. AZD7325 affects the action of a brain chemical called GABA. Brain chemicals, also called neurotransmitters, carry messages in the brain. Some studies have shown that GABA activity may be lower in some individuals with ASD. AZD7325 increases GABA activity in the brain and may be helpful to individuals with ASD.

### **2. Have other people taken this medication?**

AZD7325 was tested in 500 adults with anxiety disorders. It has not been studied in ASD.

### **3. Who is sponsoring this study?**

The study is funded by the National Institute of Mental Health. The company AstraZeneca is providing AZD7325 for this study in adults with ASD. The study is being done in three United States medical centers.

### **4. Does everyone in the study take the new medication?**

This study involves a placebo. A placebo is a pill that resembles AZD7325 in every way except it does not contain any medication. Who receives AZD7325 and who receives a placebo in the study is random. The study team does not know who will get the active medication or the placebo. It is determined by a computer program.

### **5. How long is the study and what does it involve?**

The study takes up to 12 weeks and has three parts: screening, double-blind phase and follow up. Screening involves 2 visits over a one- to two-week period in most cases. The purpose of screening is to find out if there is any medical reason or other reason that a person with ASD should not be in the study.

The double-blind phase takes about 6 weeks. During the double-blind phase, subjects will take AZD7325 or the look-alike placebo for the entire 6 weeks. We call this phase “double-blind” because the subject, the family and the study team will not know if it is the active medication or the placebo.

In case of an emergency, we can find out whether a study participant is taking AZD7325 or the placebo by calling the pharmacy at Emory.

After six weeks on either AZD7325 or placebo, participants will come in for a check-up and will stop taking the medication. A member of the research team will check on how things are going in a telephone call and then in a final visit two weeks later.

### **6. Is the medication approved by the Food and Drug Administration (FDA)?**

AZD7325 is still in an experimental phase and is not approved by the FDA. It is not on the market and cannot be prescribed outside the study. Our study has been reviewed by the FDA and we have permission to do the study.

### **7. What happens when the study is over?**

AZD7325 is not available outside the study. Adults with ASD who participate in the study will not be able to continue taking the medication when the study is over.

**8. What happens if someone starts the study and then wants to stop participating?**

Participation is voluntary. A person in the study can quit any time. If a subject decides to quit, we will set up a final check-up and talk about how to stop the medication.

**9. Will I need to stop taking medications already prescribed by my doctor?**

We will not ask participants to stop taking current medications. Some medications may interact with AZD7325. We will ask about these medications during screening. Participants taking one of these medications will not be eligible for the study.

**10. What are the most common side effects?**

The most common side effects are dizziness, sleepiness, fatigue and headache. Some subjects in prior studies complained of feeling hot or in an especially happy mood. Others described feeling drunk. The dose schedule in this study is set up to minimize side effects.

**11. What is an EEG?**

EEG stands for electroencephalogram. EEG measures brain activity and provides information on brain function. Participants wear a cap on their head. The cap has sensors that pick up electrical activity in the brain. The EEG does not hurt. There are no needles, no radioactivity or x-rays. It takes 30 minutes to fit the cap and 30 to 40 minutes for the EEG. We are using EEG in the study to learn more about the effects of AZD7325 on brain activity. Each subject will have a total of five EEGs during the study.