



No it doesn't

How can I learn more?
If you'd like to know more, please contact us via our website or ask your family physician about the aViation study.



aViation

aViation_LEAF_V2_010916



Can we help children and adolescents with autism make sense of the world?

TIME
Flies
WHEN
YOU'RE
HAVING
Fun

INFORMATION
for you and your family
about a new clinical study

Can we help your son or daughter make sense of the world?

Imagine not being able to understand facial expressions, gestures and tone-of-voice. Or finding that you can't tell the difference between a joke and facts. People with autism spectrum disorder (ASD) can face such challenges every day. That's why they can find social communication and social interactions challenging.

To date, no medications have been approved to treat ASD's core symptoms. So we're looking for 300 children and adolescents with 'high-functioning' ASD to join the aViation study. The aViation study will test an investigational medicine that blocks a hormone receptor in the brain that is linked to the control of socialization, stress, anxiety and aggression.

We'll be asking if the investigational study drug can improve social behavior and communication in children and adolescents who:

- Have ASD
- Are 5-to-17 years old
- Are 'high-functioning' (for this study, that means an IQ of at least 70)

Study length



UP TO 39 WEEKS IN TOTAL
screening period (3-8 weeks) We'll check that your son or daughter is a good fit for this study.
DOSING PHASE (24 weeks) We'll assign your son or daughter a study drug (either the investigational study drug or a placebo). They will take this for up to 24 weeks and we'll collect information about its effects.
FOLLOW-UP PERIOD (up to 7 weeks) We'll give your son or daughter two final health checks.

From time to time, new information about the investigational study drug may become available to the study team. The study team will then decide if we need to change the study's design at all.

Dosing plans

Study drugs will be assigned at random (purely by chance, like the tossing of a coin). Two out of three participants will take daily doses of the investigational study drug and the rest will take daily doses of a placebo. The placebo looks like the investigational study drug but doesn't contain any medicine.

Both the investigational study drug and the placebo are small tablets that can be swallowed whole or dissolved in liquid. You won't be told what your son or daughter's tablets contain and neither will your doctor's team (except in an emergency).

Health checks

During the study, your son or daughter will visit a study clinic with you around once every 6 weeks (about 7 times in total). This will allow the team to assess his or her:

- General health
- Communications skills
- Social skills
- Daily living skills
- Overall ASD symptoms

In between these clinic visits, a nurse will need to take some additional blood samples. To do this, they'll either visit you at your home or you'll be asked to go back to the clinic.

The data gathered during both clinic and home visits will help us decide the future of the investigational study drug; the same parent or guardian must be present each time and willing to answer questions about their son or daughter's condition and health.

FREQUENTLY ASKED QUESTIONS



"WHAT IS A CLINICAL STUDY?"

Clinical studies (also known as 'clinical trials') are scientific studies that help us make medicine better. Studies like this one compare different dosing plans to help us answer specific questions about potential new treatments. Every year, many thousands of adults and children take part in clinical studies all around the world. For more information about your son or daughter's rights as a research participant, please call Quorum Review at 888-776-9115 (toll free) or visit www.quorumreview.com.

"WILL WE HAVE TO PAY?"

You will not have to pay for any study-related treatments, lab tests or assessments. Reimbursement for travel may also be available.

"DOES MY SON OR DAUGHTER HAVE TO TAKE PART?"

Not at all. We're looking for 'volunteers'. Also, participants (or their parents or guardians) may change their mind and leave the study at a later time. Your decision will not affect your son or daughter's regular medical care and any benefits he or she is entitled to receive.

