ForPatients
by Roche

Autism Spectrum Disorder

A clinical trial to compare different doses of an investigational drug (called 'RO7017773') with a placebo (a pretend drug) in people with Autism Spectrum Disorder

A 12-Week Placebo-Controlled Study to Investigate the Efficacy, Safety, and Tolerability of RO7017773 in Participants Aged 15-45 Years With Autism Spectrum Disorder (ASD)

Trial Status	Trial Runs In	Trial Identifier
Completed	4 Countries	NCT04299464 2019-003524-20 BP41316

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This study will investigate the efficacy, safety, tolerability, and pharmacokinetics of RO7017773 in participants aged 15-45 years who have been diagnosed with ASD with a score of >/=50 on the Wechsler Abreviated Scale of Intelligence (WASI-II).

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT04299464 2019-003524-20 BP41316
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=15 Years & <= 45 Years	No

1. Why is the Aurora Borealis clinical trial needed?

Autism is a developmental condition made up of lots of different characteristics. While different autistic people experience different characteristics, there are two core characteristics: Difficulties with social interaction and communication as well as restricted and repetitive patterns of behaviors, activities or interests.

The Aurora Borealis study is evaluating an investigational drug designed to target a part of the brain that may help with these core characteristics of autism.

2. How does the Aurora Borealis clinical trial work?

This clinical trial is recruiting people with autism. People can take part if they experience difficulties with social interaction and communication as well as display restricted and repetitive patterns of behaviors, activities or interests.

The purpose of this clinical trial is to compare the effects, good or bad, of the investigational drug against placebo in people with autism. Placebo is a substance that has no effect but is designed to seem the same as the trial medication. People who take part in this clinical trial will receive either the investigational drug or a placebo.

Participants will be given the investigational drug or placebo for around 12 weeks. Participants will be seen by the clinical trial doctor every few weeks. These hospital visits will include checks to see how the participant is responding to the treatment and any side effects they may be having. Participants' total time in the clinical trial will be roughly 24 weeks. Participants are free to stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the Aurora Borealis clinical trial?

The main clinical trial endpoints (the main results that are measured in the trial to see if the medicine has worked) are the changes in social behaviors and communication as well as repetitive and restricted behaviors when they are assessed from the start to the end of the 12-week treatment period. A set of interviews and questionnaires will be used by the study doctors to measure these characteristics, skills, and behaviors.

Other clinical trial endpoints are the percentage of participants with adverse events and serious adverse events when they are assessed from the start to the end of the study.

4. Who can take part in this clinical trial?

People can take part in this trial if they have been diagnosed with autism, are 15 to 45 years of age, and struggle with communication issues and repetitive behaviors.

People may not be able to take part in this trial if they have a rare genetic form of autism or take certain medications.

5. What treatment will participants be given in this clinical trial?

Everyone who participates this clinical trial will be join one of three groups randomly (like flipping a coin) and given either:

Low dose of the investigational drug, given as pills every day for around 12 weeks

High dose of the investigational drug, given as pills every day for around 12 weeks

Placebo, given as pills every day for around 12 weeks

At this time it is not known which dose will be safest and most effective. Therefore, two different doses are tested and compared in this clinical trial.

Participants will have a 1 in 3 chance of being placed in any group.

This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given a substance with no active ingredients (also known as a ‘placebo’); it looks like the drug being tested. Comparing results from the different groups helps the researchers know whether any changes seen are a result of the drug or occurring by chance.

This is a double-blinded trial, which means that neither the participant nor the clinical trial doctor can choose or know the group the participant is in, until the trial is over. This approach helps to prevent bias and expectations about what will happen. However, the participant’s clinical trial doctor can find out which group the participant is in, if their safety is at risk.

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment may not be fully known at the time of the trial. Most trials involve some risks to the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual health care provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the trial.

Risks associated with the clinical trial

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drug used in this clinical trial. Side effects can be mild to severe and even life threatening, and can vary from person to person.

RO7017773 (the study investigational drug)

Potential participants will be told about the known side effects of the investigational drug, and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs.

The investigational drug and placebo will be given as an oral tablet (given by mouth). Participants will be told about any known side effects of oral drug administration.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

For more information about this clinical trial see the For Expert tab on the specific ForPatients page or follow this link to ClinicalTrials.gov https://www.clinicaltrials.gov/ct2/show/NCT04299464?term=bp41316&draw=1&rank=1