

CLINICAL TRIAL INVESTIGATING POTENTIAL TREATMENT FOR IRRITABILITY ASSOCIATED WITH AUTISM SPECTRUM DISORDER (ASD) IN ADOLESCENTS AGED 13 to 17

WHY IS THIS STUDY BEING CONDUCTED?

- Research has shown the gut bacteria of autistic children is different to non-autistic children. It is possible that certain bacteria derived metabolites produced in the gut may reach the brain resulting in characteristics of autism.
- We are researching an experimental treatment, AB-2004, which is designed to soak up these metabolites in the gut to reduce their entry into the brain via the blood stream. We hope this will improve autistic traits of irritability and anxiety.
- This study aims to establish an effective dose that will help improve irritability and anxiety in autistic adolescents.

TELL ME MORE ABOUT THE MEDICATION BEING RESEARCHED

- The study medication are small fine granules, which are tasteless and odourless.
- Study medication is taken 3 times a day, which your child mixes with soft food they usually eat like yogurt, ice-cream, mash potatoes.
- AB-2004 is not approved in either Australia or New Zealand, however, it is approved and marketed in other countries for chronic kidney disease and irritable bowel symptoms, but not autism.

WHAT WILL THE STUDY INVOLVE?

If you and your child are interested in participating, then the study team at the clinic will complete a screening visit to determine if he/ she is eligible to participate.

If your child is eligible, then you and your child will be invited to participate in the study which lasts for 16 weeks and include 6 in-clinic visits and 3 remote visits (telephone/ video).

Along with taking the study medication, your child will have to provide blood, urine, and stool samples. Blood will only be collected 3 times over the 16 weeks. The study doctor will also work with you and your child to complete a series of assessments that will evaluate changes associated with taking the study medication.

IF YOU OR YOUR CHILD:

Is 13-17 years old

Is on the autism spectrum

Has irritability and gut symptoms

PLEASE CONTACT

The CCTRND Team

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