Now enrolling: the Phase 3 D1AMOND study for children, adolescents, and adults with Tourette's Disorder

A quick reference guide for patient advocacy groups

Thank you for your interest in learning about the Phase 3 D1AMOND study. This fact sheet provides study details that you can share with patients or their caregivers. If patients and/or caregivers have any questions or would like to know more, please direct them to call the local study site at the number below.

What is this study?

The Phase 3 D1AMOND study is a multicenter, randomized, double-blind study of children and adolescents 6 years of age and older and adults who have Tourette's Disorder.

The Phase 3 D1AMOND study is researching a study drug called ecopipam to evaluate how it works over time and how safe it is for children, adolescents, and adults with Tourette's Disorder.

Who is this study enrolling?

This study is enrolling participants who:

- Are at least 6 years of age
- Weigh at least 18 kg (39.6 lbs)
- Have been diagnosed with Tourette's Disorder
- Have both motor and vocal tics

This is not a complete list of study requirements. The study doctor will discuss all the requirements and answer any questions.

Why is this study important?

Tourette's Disorder affects millions of children, adolescents, and adults around the world. Currently approved therapies for Tourette's Disorder sometimes come with undesirable side effects, so there is a need for more research for this condition.

How long will this study last?

Participants will be in this study for approximately 8 months and will have at least 15 visits to the study site during that time. There will also be at least two telephone appointments during the study.

D1AMOND PHASE 3

What can participants and/or their caregivers expect if they participate in the study?

In the Phase 3 D1AMOND study, there will be four study periods. First, there is a screening period, which will last up to 28 days. During the screening period, doctors will decide if individuals are eligible to participate in the study.

Next is the open-label stabilization period, which will last around 12 weeks. During this period, all participants will receive the study drug, ecopipam.

The double-blind randomized withdrawal period will follow. It will last about 12 weeks. During this period, some participants will receive the study drug, ecopipam, and some will receive a placebo. A placebo is a substance that looks like the study drug but has no study drug in it. Participants will be chosen at random (by chance, like flipping a coin) to receive the study drug or the placebo.

The final portion of the study is the safety follow-up period, which will last about 30 days.

Participants who complete the study will have the opportunity to enter an extension study where all participants will receive the study drug.

How will participants' health be monitored in this study?

Throughout all periods of the study, the health of participants will be continuously monitored through tests and assessments that may include:

- Physical exams
- Review of current medications
- Review of symptoms
- Questionnaires
- Blood tests
- Urine tests
- Electrocardiograms (ECGs) to measure the electrical activity of the heart

Not all of these activities will occur at every visit.

What are the benefits and risks of being in this study?

One benefit of taking part in this study is that participants' health will be monitored frequently. Each visit will mirror that of standard of care, and the frequency of these visits is not expected to put an undue burden on participants or their caregivers.

Is participating in this study mandatory?

Taking part in a research study is voluntary. Individuals or their caregivers may choose to join the study but leave at a later date for any reason at any time. Regardless of whether a person chooses to enroll or leave the study early, the future healthcare of that individual will not be affected.

How can patients and caregivers learn more about this study?

To learn more, please direct patients or their caregivers to contact our local study site at the contacts below. The study team can also schedule a screening appointment to explain the study in detail.

Study site contacts:

Tracy Hammer
Email: tahammer@ucalgary.ca
Phone: 403-210-7590

Iris Kathol
Email: ikathol@ucalgary.ca
Phone: 403-210-6830

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This study has been approved by the University of Calgary Conjoint Health Research Ethics Board
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