About Research Studies

Pharmaceutical companies use research studies like the ARTISTS 2 study to learn more about investigational drugs before they are made available to the public. The results of this study will provide more information about the investigational drug and its effect on Tourette syndrome. By taking part in this study, you and your child will contribute to Tourette syndrome treatment research.

For more information, please visit www.artiststudyts.com or contact:

ARTISTS 2

Let's paint a different picture for *Tourette Syndrome*

Help local doctors with the ARTISTS 2 study evaluate an investigational drug for children and adolescents with Tourette syndrome.

No one knows exactly what causes Tourette syndrome,

but we do know how it can make you or your child feel. The tics related to Tourette syndrome can be embarrassing and create anxiety. This affects everyday life, which includes learning at school or hanging out with friends.

While there are effective Tourette syndrome treatments available, these can cause side effects that keep people from using the medications. As a result, there is a need for medications that can help control tics and cause fewer side effects.

In this study, doctors are evaluating an investigational drug that may have similar effects on tics, but limits side effects. They want to compare two doses of the investigational drug to placebo, which looks like the investigational drug, but contains no active medication.

The investigational drug has not been approved for the treatment of Tourette syndrome and is only available in this study. The results of this study will provide more information about the investigational drug and whether it could one day be used to treat Tourette syndrome.

Who is eligible to participate in the ARTISTS 2 study?

To pre-qualify for this study, you or your child must:

- Be 6 to 16 years of age
- Weigh at least 44 pounds (20 kg)
- Exhibit tics or have been diagnosed with tics and/or Tourette syndrome

All study-related visits, tests, and study drugs will be provided at no cost. In addition, reimbursement for study-related travel may be provided.

What will happen during the ARTISTS 2 study?

Eligible patients will be randomly assigned (like the flip of a coin) to receive either the investigational drug or placebo. There is a 2 in 3 chance (66.7%) of receiving one of the investigational drug doses and a 1 in 3 chance (33.3%) of receiving placebo.

Patients, parents/guardians, the study doctor, and the study staff will not know the study drug (investigational or placebo) assignments. This is to prevent any opinions about the study

drugs from affecting the study results. However, in the event of an emergency, that information can be provided.

Patients will take their study drug twice a day for 8 weeks. A patient's dose will be increased or decreased during the study until an optimal dose is reached.

Total study participation will last approximately 14 weeks, which includes up to 6 visits to the study clinic for tests and assessments, as well as up to 5 telephone calls from the study staff.

What are the benefits and risks related to the ARTISTS 2 study?

While it is possible patients could experience some benefit from participating in this study, it cannot be guaranteed. However, the results of this study could help researchers better understand Tourette syndrome for future tests or treatments.

It is also possible patients could experience a side effect during this study. The study staff will review the risks and side effects related to study participation with each patient and their parents/guardians prior to the patient joining the study.

Because research studies can affect the health and safety of participants, patients will be monitored while in this study. The sponsor of this study was required to design a protocol, which explains all study procedures in detail. An independent review board responsible for participant safety reviewed this protocol and requires that it be followed exactly.