About clinical research studies

Clinical research studies, also known as clinical trials, are conducted to determine whether or not a study drug is safe and effective to treat a particular condition or group of patients.

During these studies, information is collected on the effects of the study drug being taken. Once a clinical research study is completed, regulatory agencies carefully review the information. They then decide whether the study drug should be available to patients.

There are guidelines and regulations that must be followed during clinical research studies to help protect the rights of those patients taking part. The rules also make sure the studies are conducted ethically and within approved medical standards.

What is the Kites study?

Kites, an ADVANCE study, is an international clinical research study for children aged 7 to 11 years old who are affected by Major Depressive Disorder (MDD).

The study will evaluate the effectiveness of an investigational medication, called vortioxetine, in the prevention of relapse in pediatric patients with MDD. In the rest of this brochure, we will use the term “study drug” when referring to vortioxetine. The study will also look at the long-term safety and how well children tolerate the study drug.

Why take part?

Taking part in a clinical research study does not necessarily mean your child’s condition will improve; there are potential risks in the form of side effects as well as potential benefits from taking part in a study. They may experience side effects like nausea (feeling sick); any side effect experienced should be reported to the study team.

By taking part in the Kites study, your child will be contributing to the development of an investigational study drug. The potential benefits of participating may include study-related professional care and the chance to learn more about your child’s condition.

For more information about the Kites study, please contact:

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Is your child troubled by depression?

IRB Approved at the Protocol Level Feb 19, 2021

Consider allowing your child to take part in the Kites study, a clinical research study for children with Major Depressive Disorder.

Kites
an ADVANCE study

What will my child have to do during the Kites study?

If you are interested in your child taking part in the Kites study, you will both need to meet with a member of the study team, either a doctor or nurse, at a research center that is near to your home. The center will usually be located in a hospital or clinic.

The study team will explain the purpose of the study, the possible risks and benefits and what will be expected of you and your child. If you agree, you will be asked to sign a form stating that you understand the study and that you give your consent to your child's participation. Once you sign the form, your child will have some health exams and the study team will ask questions to see if they qualify for the study. This screening period may last up to 2 weeks.

If your child is suitable for the study, they will move onto the treatment periods.

Treatment periods

There are two treatment periods as part of the Kites study.

In the first treatment period, your child will receive the investigational study drug, every day for 12 weeks.

If your child's condition improves during the first treatment period, they will be eligible to enter the second treatment period. In this treatment period, all participants are assigned randomly (like flipping a coin) to receive either the study drug capsules or placebo capsules. Placebo looks like the study drug but contains no active medication ingredients. Neither you, your child nor the study team will know which your child is taking. Your child will take either the study drug or placebo every day for 26 weeks.

While your child is in the study, the research team will keep a close eye on their health. They will ask your child questions about how they are feeling and what other medications they are taking. They will also examine your child and take blood and/or urine samples for testing. If your child's condition worsens during the second treatment period, they will be withdrawn from the study.

Participating in this study is voluntary; you and your child can choose to leave the study at any time. Patients whose condition worsens, or patients who decided to withdraw from the study for any reason, will still receive proper care from their doctor. This care is not part of the study and the costs of care will be the parent or caregiver's responsibility.

Safety follow-up visits

The safety follow-up visit helps to record any side effects that happened or changed during the safety follow-up period as well as the end of the treatment period. This visit will occur 4 weeks after the last treatment dose.

Who can take part in this study?

Your child may be suitable to join the Kites study if he/she is:

- Aged between 7 and 11 years old
- Diagnosed with Major Depressive Disorder (MDD)
- In need of pharmacological (medicinal) treatment as an outpatient
- Available to take part in the study for up to 44 weeks

These are the main criteria for entering the Kites study. There are a few other requirements your child will need to meet to make sure they are suitable for the study once you and your child have met with the study doctor.

Children who have completed a previous Kites study may be able to take part in this new study.

All study-related care, visits, and study drug will be covered during the study and provided at no additional cost.

Kites
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