Frequently Asked Questions

WHAT IS A CLINICAL TRIAL?

A clinical trial is a type of research study designed to evaluate whether an investigational drug is safe and effective for use in humans. Participants are given specific medical treatments and researchers closely monitor the results to help determine if the drug should be approved for wider use. The U.S. Food and Drug Administration (FDA) has strict rules that govern how clinical trials are conducted and requires that an investigational drug be proven safe and effective before it can be widely used in the United States.

WHAT IS AN EXPERIMENTAL DRUG?

An experimental drug is a drug that has not been approved by the U.S. Food and Drug Administration (FDA) but can be administered to people in a clinical trial for research purposes.

WHAT TYPE OF CLINICAL TRIAL IS ARISE?

ARISE is a clinical trial evaluating the safety and efficacy of KarXT.

Taking part in this study may or may not help treat your schizophrenia. Your health could improve, stay the same, or get worse. However, the data we get from you during this study may help doctors learn more about the study drug, schizophrenia, and this may help future patients.

There is no cost to participants to be in the study and there is no maximum duration for this trial. You can continue with your cycles of treatment until any of the following occur: your disease worsens, you decide to no longer participate in the trial, the trial doctor decides you should no longer participate in the trial, the trial sponsor decides to stop the trial.

arise
INADEQUATE RESPONSE IN SCHIZOPHRENIA

LEARN MORE:

[study website]

CONTACT INFORMATION:

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A Clinical Research Study for Schizophrenia

arise
INADEQUATE RESPONSE IN SCHIZOPHRENIA

Is your daily life being disrupted by the effects of Schizophrenia?

Learn more about this study opportunity!

What is Schizophrenia

Schizophrenia is a serious mental disorder which affects 1% of the world's population. People with schizophrenia interpret reality abnormally and this may result in some combination of hallucinations, delusions, and extremely disordered thinking and behavior that impairs daily functioning and can be disabling. Schizophrenia involves a range of problems with thinking, behavior, and emotions.

Symptoms are described in terms of positive, negative, and cognitive symptoms. The positive symptoms of schizophrenia are the same for any psychosis and are sometimes referred to as psychotic symptoms. These may be present in any of the different psychoses and are often transient making early diagnosis of schizophrenia problematic.

About KarXT

The goal of the study is to see if KarXT combined with your current schizophrenia medicine works better than your current medicine alone. The study is also planned to see if both drugs taken together are safe and well accepted by patients with schizophrenia.

KarXT is a novel combination of xanomeline tartrate and trospium chloride and is being developed for treating people like you with schizophrenia. It is not yet approved for treating schizophrenia and can only be used in a study like this one.

KarXT may or may not help treat your schizophrenia. Your health could improve, stay the same, or get worse. However, the data we get from you during this study may help doctors learn more about the study drug, schizophrenia, and this may help future patients. KarXT is an adjunctive medication; participants will not need to stop taking their current oral antipsychotic drugs (APDs).

Why Should I Participate?

By participating in ARISE you will:

- Play an integral role in the advancement of schizophrenia research
- May be able to take control of your acute symptoms
- Receive care from a local doctor at no cost to you.

What to expect from the ARISE Study

At the beginning of the trial, participants will be asked to sign an electronic Informed Consent Form (eICF)*, after which they will undergo a screening period.

During this initial 5-week screening period, participants will continue to take the same APDs they were taking before they came into the study. There will be two initial screening visits, the last of which will be scheduled 2 weeks prior to the Treatment Period. After successfully completing the Screening Period, participants will start double-blind treatment of either adjunctive KarXT or adjunctive placebo.

During the 6-week Treatment Period participants will be expected to attend at least 6 in-person visits at the study site. While in the study, they will take KarXT or the placebo 2 times a day, except for the first and last days where they will only take 1 dose. Participants will also be asked to use a smartphone app which will be used for study drug administration, monitoring and schizophrenia-related symptom assessments.

At the end of the study, week 7, there will be a final safety follow-up visit. Some participants may be eligible for an open label study and will therefore not need to attend this follow-up visit.

** Informed consent is the process of providing participants with key information about a clinical trial before they decide whether to accept the offer to take part and continue throughout the trial. The trial team provides an informed consent document that includes details about the trial, such as its purpose, how long it's expected to last, tests or procedures that will be done as part of the research, and who to contact for further information. The informed consent document also explains risks and potential benefits.*

About the Study

WHAT IS THE ARISE CLINICAL STUDY?

This clinical trial will test the effectiveness, safety, and tolerability of KarXT, an oral adjunctive medication, for the symptoms of schizophrenia.

- Some participants will receive the investigational medication, other participants will receive a placebo**
- Participants will track medication dosage through a Smartphone app.
- Trial will last up to 12 weeks

OPEN LABEL EXTENSION

Once patients have completed the treatment period of the ARISE study, they may be eligible to participate in an open label extension (OLE) study of KarXT. During the OLE study all participants would receive the study drug regardless of if they received the study drug or a placebo during the ARISE study.

How can I participate in the study?

YOU MAY BE ELIGIBLE TO PARTICIPATE IF YOU:

- Primary diagnosis of schizophrenia established by a comprehensive psychiatric evaluation based on the DSM-5
- Have identified a reliable informant and/or clinical support team willing and able to assist with study activities
- Participant may not be eligible if they have a history of moderate to severe alcohol use disorder or substance use disorder within the past 12 months

Clinical Study eligibility requirements will apply, and only a qualified healthcare professional can determine if you or a loved one are eligible to participate in the study.

*** The placebo will look exactly like the investigational medication but will not have active ingredients.*

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