STILL STRUGGLING WITH SCHIZOPHRENIA?

Information about DayBreak – a clinical research study for people with treatment-resistant schizophrenia

DayBreak

MANAGING SCHIZOPHRENIA CAN BE A STRUGGLE

There are a lot of schizophrenia medications available. But many people still struggle to manage their condition. Some do not benefit enough from currently available drugs (what we call 'treatment-resistant' schizophrenia). While others experience side effects that outweigh any benefits seen. So researchers are carrying out clinical research studies to test possible alternatives – studies like DayBreak.

DayBreak is looking to recruit people who are:

- At least 18 years old
- Struggling with schizophrenia despite trying at least one medication
- Seeing a psychiatrist in an in-patient or out-patient setting
- Under the care of someone who will offer support during the study

This leaflet will tell you about the study. It will help you decide if you would like to find out more. If you have any questions, please contact us for a confidential no-obligation chat.

CLINICAL RESEARCH STUDIES IN BRIEF

Why do we carry out clinical research studies?

Every year, thousands of people take part in clinical research studies. These studies help us make medicine better by testing investigational medications in a controlled way. Various groups review and OK each study's plan before it begins. Their job is to make sure that the safety and rights of all participants will be protected.

Is taking part compulsory?

No one can be forced to join a clinical research study – participation is entirely voluntary. Also, no one can be made to stay on a study if they change their mind and participants may leave a study at any time.

Will participants be paid?

During DayBreak, reimbursement for study-related travel costs may be available. The study team can tell you more.

ABOUT THE DAYBREAK STUDY

Some schizophrenia medications affect levels of a 'brain messenger' called dopamine. Others also affect serotonin (another brain messenger). But our investigational medication affects a third brain messenger. This three-pronged approach may help people who are struggling to control their condition using current treatments.

Among other things, the DayBreak study will try to answer the following questions:

- Does the investigational medication reduce symptoms?
- What effect does it have on functioning and quality-of-life?
- Does it cause any side effects?

We will randomly (by chance) divide 675 participants into groups. These groups will follow different dosing regimens during the course of two study periods. By comparing the results of these groups, we will be able to answer our questions about the investigational medication.

	STUDY PERIOD A	**STUDY PERIOD B**
How long will it last?	6 weeks	10 weeks
What will participants take?	Tablets containing either risperidone OR olanzapine (approved schizophrenia medications)	Tablets containing either the investigational medication OR the medication assigned during period A
What is the aim of this period?	To make sure that participants truly are treatment resistant	To assess the effects of the investigational medication
Is there anything else that I should know?	The study team will know which medication participants are taking, but participants themselves will not; current schizophrenia medication use will be carefully reduced to zero during the first week of this period	Neither participants nor the study team will know which medication participants are taking; two out of every three participants will be assigned the investigational medication.

MONITORING THE HEALTH OF PARTICIPANTS

Participant safety is our top priority. That is why all participants will have their health and condition monitored during regular clinic visits. During study periods A and B, these visits will take place around once every 1-2 weeks. They may include assessments such as:

- Blood and urine sampling
- Vital signs checks
- Weight and waist measurements
- Heart activity checks
- Symptom questionnaires
- Quality-of-life questionnaires

It is very important that participants attend all visits. The study team should be notified as soon as possible if an appointment needs to be rescheduled.

POTENTIAL SIDE EFFECTS

We cannot guarantee that taking part in the DayBreak study will lead to an improvement in a participant's condition. Their symptoms may improve, stay the same or get worse. Also, it is important to note that the medications being used in this study (including the approved medications) may cause side effects. However, the study team will regularly monitor participants in order to check their health and schizophrenia status.

LEARN MORE ABOUT DAYBREAK

To learn more, please contact us for a confidential no-obligation chat. We can tell you more about the study and schedule a 'screening' visit for anyone who would like to join. During the screening visit, we will explain the study in detail and (once your written consent has been obtained) carry out a health check to assess suitability.

Once again, please be reassured that participation is entirely voluntary – talking to us or attending a screening visit in no way obliges someone to join the study.

Study team contact details:

Finger Lakes Clinical Research

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