DREaM

Disease Recovery Evaluation and Modification (DREaM) Study

A Study to Compare Disease Progression and Modification Following Treatment With Paliperidone Palmitate Long-Acting Injection or Oral Antipsychotics in Participants With Recent-Onset Schizophrenia or Schizophreniform Disorder

The Study

The purpose of this study is to compare the effectiveness of paliperidone palmitate delivered as 1-month and 3-month injectables versus oral antipsychotics on disease progression and disease modification in participants with recent-onset schizophrenia or schizophreniform disorder measured by assessing symptoms, cognition, functioning, and (in selected centers) brain imaging.

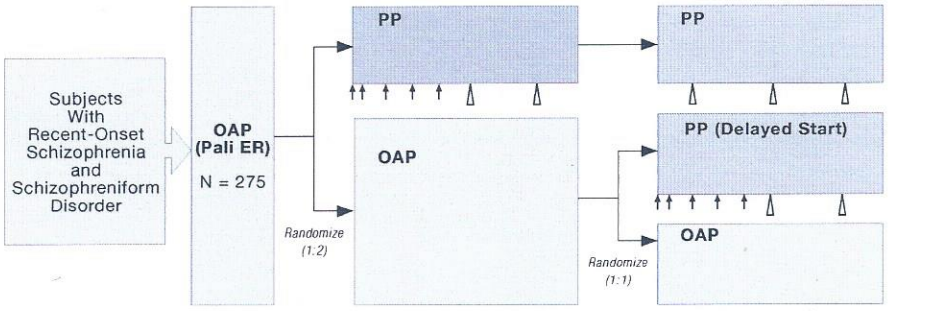
The Study Drug

All of the drugs used in this study are approved in the U.S. by the FDA for the treatment of schizophrenia. All patients in this trial will be on active antipsychotic treatment. The drugs used in this trial are 1-month and 3-month injections of paliperidone palmitate and seven commonly used oral antipsychotics. Subjects randomized to receive the long-acting injectable will start with the 1-month injectable for 4 months prior to transitioning to the 3-month injectable.

The Study Phases

The study will include 275 participants and last approximately 20 months. This includes an initial 2-month treatment with an oral antipsychotic followed by two sequential 9-month treatment periods with either the long-acting injectable or oral antipsychotics.

Study Schematic



OAP = Oral antipsychotic

PP = Paliperidone palmitate (1-month and 3-month injections)

↑ = PP1M injection

Δ = PP3M injection

Key Inclusion Criteria

- Men and women, aged 18 to 35 years
- A current diagnosis of schizophrenia or schizophreniform disorder
- First psychotic episode within the last 24 months
- Has a responsible individual (such as a significant other, relative or friend) who can assist study staff
- Has a stable residence

Key Exclusion Criteria

- A current DSM-5 diagnosis of dissociative disorder, bipolar disorder, major depressive disorder, schizoaffective disorder, autistic disorder or intellectual disabilities
- Has a history of lack of response to oral or LAI risperidone or paliperidone
- Has a history of neuroleptic malignant syndrome

Additional criteria apply.

If you have patients you believe may qualify for this study, or for more information, please contact:

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