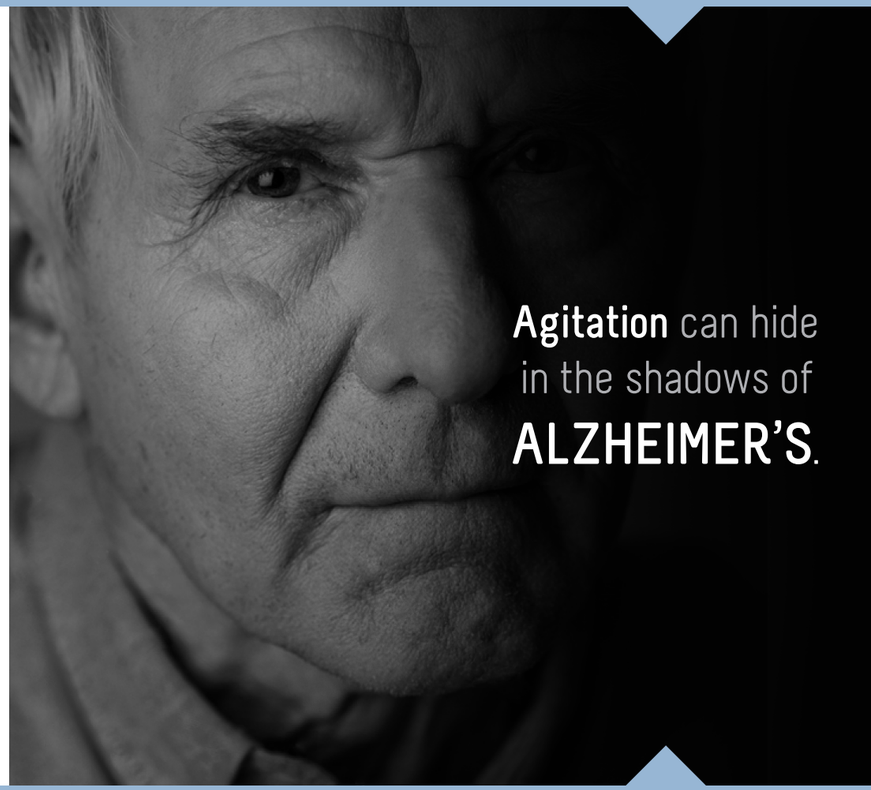
About Research Studies

Research studies help pharmaceutical companies learn more about investigational drugs before they are made available to the public. The results of this research study will provide more information about the investigational drug and its potential as a possible treatment for agitation related to Alzheimer's disease. By taking part in this study, you and your loved one will contribute to agitation related to Alzheimer's disease treatment research.

To learn more, please contact:



If you have a loved one with Alzheimer's disease who has shown signs of agitation, you may want to learn more about this research study of an investigational drug.

It can be a test of your patience when a loved one with **ALZHEIMER'S** shows signs of **AGITATION.** One minute they're pleasant and the next they're emotionally distressed, restless, or aggressive. You do what you can to settle them down, but it's not easy.

Because there are no approved long-term treatments for managing agitation in adults with Alzheimer's, your loved one is more likely to have verbal or physical confrontations. These confrontations can be unsafe for themselves, you, and others nearby. As a result of this unmet medical need, doctors and researchers are conducting this research study.

In this study, local doctors are evaluating an investigational drug that is being developed for the treatment of agitation related to Alzheimer's disease. They want to compare the investigational drug to placebo, which looks like the investigational drug, but contains no active ingredient.

The investigational drug has not been approved to treat agitation related to Alzheimer's disease. However, the drug has been found to be safe in patients and approved to treat adults with schizophrenia. It has also been approved to treat adults with major depressive disorder (MDD) when it is taken in combination with antidepressants.

The results of this study will provide more information about the investigational drug and whether it could one day be a potential treatment option for agitation related to Alzheimer's disease.

At the end of the study, patients may have the opportunity to participate in an open-label study in which all patients will receive the investigational drug.

Who is eligible to participate in this study?

To pre-qualify for this study, patients must:

- Be between 55 and 90 years of age
- Have been diagnosed with Alzheimer's disease
- Have had a diagnosis of agitation

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

What will happen during this study?

Eligible patients will be randomly assigned (like tossing a coin) to receive either the investigational drug, or placebo. Patients have a 2 in 3 chance of receiving the investigational drug and a 1 in 3 chance of receiving placebo.

To prevent opinions about the study drug from affecting the study results, the study is designed so that patients, the study doctor, and the study staff will not know the study drug assignments. However, in the event of an emergency, this information can be provided.

Patients will take their study drug once a day for 12 weeks. Patients will also be asked to visit the study clinic up to 9 times for tests and evaluations. Total study participation will last between 16 and 22 weeks, which includes screening for eligibility, treatment, and follow-up.

What are the benefits and risks related to this study?

While patients may benefit from participating in this study, that cannot be guaranteed. However, information collected from this study may help patients with agitation related to Alzheimer's disease in the future.

It is also possible patients could experience a side effect during this study. The study staff will review known study risks and side effects with all patients before they join the study.

Patients will be monitored by the study staff during this study. The study sponsor was required to design a protocol, which explains the study in detail. An independent review board responsible for patient safety reviewed and approved this protocol and requires that it be followed exactly.