ITI-1284-201 Study Information

This brochure contains information about the ITI-1284-201 Study for caregivers of people with Alzheimer's disease who are experiencing symptoms of psychosis. This information should help you decide whether you and the person you care for may want to take part in the study.

What is a clinical research study?

A clinical research study is a medical study that helps to answer important questions about a potential new drug, such as:

- Does it work?
- What amount, or dose, may work best?
- How safe is it?
- Are there side effects?

All drugs must be tested in clinical research studies before they can be approved to prescribe to patients. Without people taking part in these studies, we would have no new drugs.

The study doctor's name and contact information are on the back of this brochure. They can answer any questions you may have about research or the specific details of this study.

Deciding to take part in a clinical research study is your decision. If you have any questions, you can contact the study team using the information provided in this brochure.

About psychosis associated with Alzheimer's disease

According to the World Health Organization, there are more than 55 million people who live with dementia across the globe. Alzheimer's disease is the most common form of dementia and contributes to 60–70% of all dementia diagnoses.

Changes in mood and behavior are common symptoms of Alzheimer's disease. Sometimes the symptoms include:

- believing things that are not true (delusions)
- believing that someone is trying to harm them (paranoia)
- seeing or hearing things that others do not see or hear (hallucinations)
- uneasiness or restlessness (agitation)
- showing aggression towards a person.

These symptoms may mean that your loved one has psychosis associated with Alzheimer's disease. Psychosis is not uncommon for people diagnosed with Alzheimer's disease. Up to 60% of people with Alzheimer's disease may experience symptoms of psychosis. Psychosis can severely affect the quality of life of people with Alzheimer's disease, their families, and the people that care for them.

About the ITI-1284-201 Study

There are no drugs currently approved to treat symptoms of psychosis in Alzheimer's disease. The main purpose of the ITI-1284-201 Study is to look at how safe a potential new drug (investigational study drug) is and whether it works to reduce symptoms of psychosis in people with Alzheimer's disease.

The investigational study drug has been designed to act on chemicals in the brain, called serotonin and dopamine. These chemicals help to regulate different functions, including thoughts, feeling, and emotions. This study will see if changing the levels of serotonin and dopamine could decrease the symptoms of psychosis.

What will the ITI-1284-201 Study involve?

If you and the person you care for take part, you will both be in the ITI-1284-201 Study for up to 3.4 months.

The study will involve **up to 9 study visits** (7 in-person visits and 2 telephone visits). There are 3 parts to the study, including a:

- screening period (lasting up to 4 weeks) – 1 study visit
- study treatment period (lasting about 6 weeks) – 7 study visits
- follow-up period (lasting about 4 weeks) – 1 study visit.

The person you care for will be randomly (by chance) assigned to take either the investigational study drug or placebo once a day. The placebo looks the same as the investigational study drug but contains no active ingredients. Together, the investigational study drug and placebo will be called the "study drug."

Up to 3.4 months

Who can take part?

The person you care for may be able to take part if they:

- are 55 years of age or older
- have been diagnosed with Alzheimer's disease and are experiencing symptoms of psychosis
- have at least 1 caregiver who will be able to support them during the study.

What does a caregiver do in this study?

A caregiver is a relative, housemate, close personal friend, or professional caregiver of the person living with Alzheimer's disease.

Caregivers play an important role in this study. They will:

- help participants take the study drug and report compliance to the study doctor
- record any symptoms seen between the study visits in the caregiver diary
- talk to the study doctor about the symptoms of the person with Alzheimer's disease and answer questions on any changes in medications and health
- attend all study visits with the person with Alzheimer's disease.

Caregivers do **not** need to be legal representatives of the people they care for.

Caregivers in the study will be provided with training about:

- how to complete the caregiver diary
- what will happen during the study
- the use of placebo in the study.

What else do I need to consider?

- You and the person you care for do not have to take part in the study if you do not want to, and you can both stop taking part at any time.
- You and the person you care for will not be paid to take part in this study, but you may be reimbursed for reasonable travel costs.
- All study drugs and study-related tests will be provided at no cost to the person you care for.
- A team of doctors and nurses will monitor the health of the person you care for during the study.

How do I get more information?

To find out more, contact the study team using the information provided here. Study participation is voluntary. By contacting us, you and the person you care for are under no obligation to take part in the study.

Homestead Associates in Research

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