Alzheimer's Disease

TrialSpark

Are you one of the millions of Americans affected by agitation symptoms associated with Alzheimer's Disease?

The Sunrise Alzheimer's Disease study is exploring an investigational medication for individuals experiencing agitation symptoms associated with Alzheimer's Disease.

TrialSpark

Alzheimer's Disease is the most common cause of dementia. Along with memory problems, there are certain behavioral and psychological symptoms of dementia (BPSD), including psychosis, apathy, hyperactivity, agitation, aggression, sleep disorders or depression experienced by patients.[1]

The purpose of this clinical research study is to assess an investigational medication to see if it may reduce agitation symptoms in patients with Alzheimer's Disease.

1 https://www.uptodate.com/contents/management-of-neuropsychiatric-symptoms-of-dementia

Brought to you by:

TrialSpark

sunrise

Alzheimer's Disease and Agitation Symptoms

Alzheimer's Disease is a disease of the brain that causes problems with memory, thinking and behavior. It is not a normal part of aging.

Common symptoms include:

- Memory impairment (most common early symptom)
- Diminished ability to make decisions involving judgment or problem solving
- Impairments in other cognitive areas, such as language impairment
- Behavioral and psychological symptoms, such as apathy, social disengagement, irritability, and agitation

Agitation is a behavioral symptom that can be present in patients with Alzheimer's Disease. Behaviors can include resisting help from others (i.e., with daily activities), being uncooperative or stubborn (insistence on having their own way), screaming or shouting, cursing angrily, hitting self or others, kicking, pushing, throwing objects, or slamming doors.

Currently there are no FDA approved medications used to treat agitation symptoms in Alzheimer's Disease in the US.

Key Trial Details

For the Sunrise Alzheimer's Disease study, participants have a 50% chance of receiving the study medication and a 50% chance of receiving a placebo. Neither the participant nor the investigator will know whether the participant is on the active medication or a placebo.

The placebo is a medication that doesn't have any active medical ingredients. Neither the study staff nor you will know which group you are in. However, in case of an emergency the doctor can quickly find out.

The investigational medication or placebo will be in the form of an oral medication, taken once daily at bedtime over a 6-week study treatment period.

Key Trial Details (continued)

This study will be conducted under the supervision of a licensed doctor. Participation is voluntary, and the participant has the option to stop at any time.

Eligibility Requirements

An eligible participant for this study must:

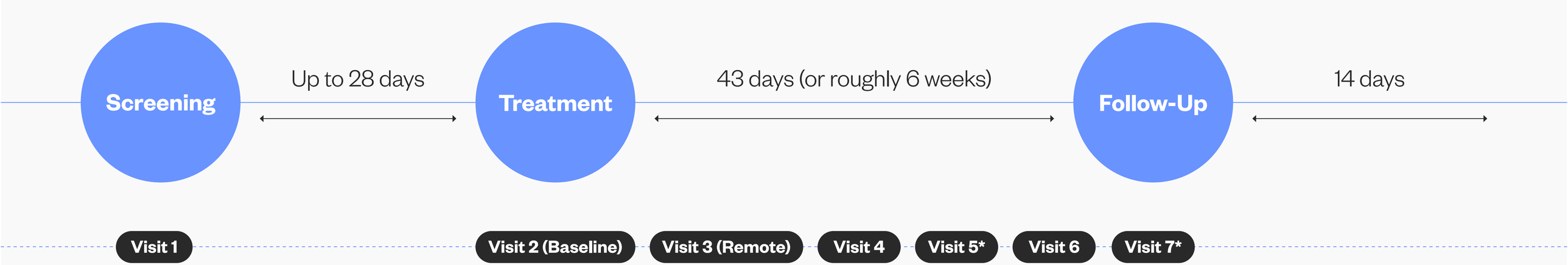
- Be 55-85 years old
- Have been diagnosed with Alzheimer's Disease by a doctor
- Have an available study partner who can be present for all study visits
- Have developed an increased frequency of symptoms of agitation after Alzheimer's Disease diagnosis. Agitation can include one or more of following behaviors:
  - Resisting help from others (i.e., with daily activities), being uncooperative or stubborn (insistence on having their own way), screaming or shouting, cursing angrily, hitting self or others, kicking, pushing, throwing objects, or slamming doors

Additional eligibility criteria will be assessed by the study doctor or staff during the screening process prior to being enrolled in the study and receiving any investigational medication. Not all individuals will qualify to participate.

What does participation look like?

Timeline: 12 Weeks Total

Participation in the study will last 12 weeks in total and consists of three parts:



* Visits have the option to be remote.

Participation Details (continued)

Screening (4 weeks)
If interested in the study, you will be asked to review and sign a consent form to make an educated decision about whether to participate in the trial. Once signed, the study doctor will perform assessments to confirm that you may be eligible to participate.

Treatment (6 weeks)
The study medication is being evaluated to determine if it is safe and effective in reducing agitation symptoms in patients with Alzheimer's Disease. It is an oral medication that is taken every night. To monitor safety and study progress, certain study visits will include: collection of medical history information, physician exams, behavioral/psychiatric questionnaires, blood draws, and electrocardiograms (ECGs). Other tests and assessments will be conducted by the study site. These will be discussed with you prior to participation.

Follow-up (2 weeks)
After study treatment ends, the study doctor will continue to follow up with you for 2 weeks to thoroughly monitor and evaluate participant safety.

Potential Benefits of Participating

May help advance Alzheimer's Disease research.

The information and knowledge gained from this study could help others affected by Alzheimer's Disease in the future.

May receive reimbursement for study-required travel to study visits.

Access to Brief Psychosocial Therapy (BPST). BPST involves regular interactions between the study partner and the participant based on a plan designed specifically for them to ensure the participant receives quality social interaction that they find interesting and engaging.

Potential Benefits of Participating (continued)

Participation is 100% optional and the study team will discuss all benefits and risks with you in more detail. Participants are able to withdraw consent at any time without affecting quality of care.

Potential Risks of Participating

If the participant receives the placebo (the inactive medication) as part of this study, their behavioral and/or psychological symptoms related to Alzheimer's Disease may not improve or may get worse.

If the participant is taking medicines for behavioral and/or psychological symptoms related to Alzheimer's Disease, they may be asked to stop taking these. This is called a wash-out. During this time, participant symptoms may not improve or may get worse. If symptoms get worse, tell the study doctor immediately.

There may be side effects associated with taking the investigational medication.

The study doctor will discuss all potential risks and side effects, both known and the potential for unknown, with you during an in-person screening visit prior to your potential participation in the study.

Information for Your Physician

This page contains information for the physicians of patients who are considering this research opportunity.

TrialSpark is helping to connect patients and physicians with the Sunrise Alzheimer's Disease study.

- If you have been approached by a patient or their caregiver about this Alzheimer's Disease research opportunity and you are seeking additional information about the study, we encourage you to reach out to TrialSpark's Medical Team at **(646) 776-3858**.

- If you are treating additional patients whom you think would be eligible for this research opportunity, TrialSpark can assist you in referring them to the study.

Please complete a contact form at

alzheimerstrial.org/physicians

Someone from the TrialSpark team will reach out to you with more information. Thank you for your interest in contributing to research!

TrialSpark

TrialSpark is a technology-driven pharmaceutical company helping to match patients with studies.

Thank you for your interest in contributing to clinical research. Study volunteers like you may lead to medical advancements.

More Information

Contact