

Do you have a loved one with agitation associated with Alzheimer's dementia? Is their agitation becoming overwhelming?

ASPECT™ Study

Agitation Associated with Alzheimer's Dementia Clinical Study

Agitation is a common and serious problem among people living with Alzheimer's dementia. Examples of some easily identifiable agitated behaviors are:¹

Restlessness	Pacing/aimless wandering
Screaming	Kicking
Shouting	Hitting others or self
Throwing things	Pushing people
Resistiveness	Hurting self or others
Constant unwarranted requests for attention or help	Tearing things or destroying property

In this study, researchers want to find out if an investigational drug called AVP-786 is safe and effective (useful) in managing agitation in adults with Alzheimer's dementia, when compared to a placebo. An investigational drug is a drug that has not been approved as a treatment by any health authority. A placebo is an investigational drug look-alike, but it has no active ingredient; taking placebo is the same as not taking anything. Throughout this flyer, the term "study drug" refers to either AVP-786 or placebo.

Study participants will be randomly assigned to receive either AVP-786 or placebo. The study drug will be provided as capsules to be taken by mouth, twice a day.

To be eligible for this study, a potential participant must:

- Be between the ages of 50 and 90
- Have a diagnosis of probable Alzheimer's disease
- Have moderate-to-severe agitation that interferes with daily life
- Have a caregiver who spends a minimum of 2 hours per day, 4 days per week with them and is willing and able to comply with all study procedures

This is not a complete list of study requirements. The study doctor will review all requirements with potential participants and their caregivers. The study drug and any study-related procedures and exams will be provided at no cost to participants.

If you are a caregiver for a person with Alzheimer's disease, find out if they might be eligible for this study by visiting www.ASPECTTrial.com for more information.

If interested, please e-mail the UCSD ASPECT™ Study Team at ClinicalTrialsADRC@health.ucsd.edu.

Reference: 1. Cummings J, Mintzer J, Brodaty H, et al. Agitation in cognitive disorders: International Psychogeriatric Association provisional consensus clinical and research definition. *Int Psychogeriatr.* Jan 2015;27(1):7-17. doi: 10.1017/S1041610214001963.