About TBI

Traumatic brain injury (TBI) is a complex injury with a broad spectrum of symptoms and disabilities. The impact on a person and his or her family can be devastating. The most troublesome behavioral symptoms are aggression, agitation, or irritability; patients and their families find these disruptive behaviors difficult to accommodate. Aggressive behavior occurs in 40–70% of TBI cases, and is severely destructive to patients and their caregivers.

In the United States (US), there are 204 TBI-related emergency room (ER) visits, 33 TBI-related hospitalizations, and 6 TBI-related deaths every hour. In 2010, there were more than 2.5 million ER visits, 280,000 hospitalizations, and 50,000 deaths related to non-military TBI—either TBI alone, or TBI in combination with other injuries. Of the patients brought to an ER for TBI, 87% were treated and released from the ER, 11% were admitted to hospitals, and 2% died.

Currently, there are no medications approved by the United States Food and Drug Administration (FDA) to treat aggression, agitation, or irritability in patients with TBI. For that reason, participation in the AVP-786 TBI Research Study could help advance new future treatment options for this condition.

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What is the AVP-786 TBI research study?

The AVP-786 TBI research study is currently evaluating the safety and effectiveness of AVP-786 for neurobehavioral disinhibition in patients with Traumatic Brain Injury (TBI) including aggression, agitation or irritability.

About the study

Qualified participants will be required to attend about 7 clinic visits over approximately 16 weeks with their caregiver. In addition to evaluations, each study visit will also provide an opportunity for the participant and caregiver to meet with the study team to share experiences and ask any questions.

The study will include:

- Study-related medical exams and assessments at no cost
- Potential compensation for time and travel

To be eligible for this study, patients must:

- Have experienced at least one traumatic brain injury (TBI) at least 9 months ago
- Have symptoms of aggression, agitation or irritability after injury
- Be between 18 and 70 years of age
- Have a caregiver able to attend all study visits
- Not be living in a nursing home

How will the participant’s rights and medical safety as a study participant be protected during the research study?

Research studies must follow strict ethical and legal standards. In addition, the US federal government and other global health authorities regulate clinical research with built-in safeguards to protect study participants. Our study has been reviewed and approved by an external Ethical Review Board (Committee) that oversees the institution where this study is being conducted.

Can the participant stop the research study before the study is completed?

Yes. Participants can withdraw from the study at any time. The participant will be asked to notify the study doctor, give reasons for the participant stopping the study, and follow through with the study exit process. In addition, the participant’s doctors may also recommend stopping study participation based on their assessment of the patient’s clinical condition.

What if there is a hard time getting the participant to and from the study appointments due to transportation issues?

If there is any issue that comes up, talk with the study team (doctor and staff) at the study site. They may be able to help assist with transportation issues.

Can the participant still see his or her regular doctor(s) during the research study period?

Yes. The participant can still continue regular visits with his or her doctor(s) but will have to inform the study team or doctor of any change in medication(s). The participant must notify their regular doctor of his or her participation in the research study.

Will the participant be able to stay on his or her current medications?

The participant may be able to stay on his or her current medication(s). The study team will discuss participant’s current medication(s) and potential participation in the study. However, if the participant is taking an allowed medication, it is important to continue to take these on a regular basis at the same dose.

What is unique about aggression, agitation or irritability associated with TBI?

There are no medications currently approved by the FDA to treat aggression, agitation, or irritability in TBI; behaviors that are the cause of significant burden for both participants and caregivers. Treating these behaviors is an important step in allowing participants to return to behaving more like their usual selves.

How does a research study work?

The participant’s health history and present symptoms will be evaluated at the beginning of the research study. If the participant is potentially eligible to participate, study instructions will be given to the caregiver. Each participant will be monitored carefully throughout the research study by the study team (doctor[s] and staff).