

About COGNIShunt® and Alzheimer's disease

This fact sheet is provided by the Alzheimer's Association for your information only and does not represent an endorsement of COGNIShunt®.

What is COGNIShunt?

COGNIShunt® is a device under investigation as a possible treatment of Alzheimer's disease. It is designed to drain cerebrospinal fluid (CSF) from the skull and into the abdominal cavity. CSF is the protective fluid that fills the empty spaces around the brain and spinal cord.

COGNIShunt is similar to the shunt used to treat hydrocephalus, a condition in which an accumulation of CSF results in enlargement of the skull and pressure on the brain.

COGNIShunt is not commercially available for sale or distribution. It is being evaluated per an Investigational Device Exemption (IDE) granted by the U.S. Food and Drug Administration. An IDE permits a device to be shipped in interstate commerce for clinical investigation to determine its medical safety and effectiveness.

What is the premise of a shunt treatment?

CSF is naturally produced and absorbed, but the cycle of "refreshing" declines with age. The researchers investigating the shunt procedure have hypothesized that toxic factors may accumulate in the CSF of an individual with Alzheimer's, contributing to brain cell damage. These factors may include beta-amyloid protein fragments and abnormally altered tau proteins. The shunt treatment is expected to drain off toxic elements and allow the CSF to be replenished.

What results have been reported to date?

Research results of a Phase I/II pilot trial were published in *Neurology* in October 2002 ("Assessment of low-flow CSF drainage as a treatment for AD: Results of a randomized pilot study." *Neurology* 2002, 59: 1139–1145). In this study, 15 participants were randomly selected to receive the shunt implantation, and 14 people received no investigational treatment. All participants had been diagnosed with mild to

moderate Alzheimer's disease. Subjects were followed for one year. The primary objective of the pilot study was to assess the safety of the shunt procedure. Side effects among the 15 people receiving the surgical treatment included seizures (2 participants), shunt infection (1), small injury in the abdomen during surgery (1), severe postoperative headache (1), postoperative pain (8), nausea (7), headache (5), abdominal pain (5), and blockage in a shunt (3).

Cognitive assessment tests were done every three months. Researchers noted a trend that symptoms were stabilized in people who received the treatment and a decline in people who did not receive treatment. The assessment of effectiveness included 11 people who received the shunt and 12 people who did not. This sample is too small to make definitive statements about the benefits of the treatment.

What additional research is needed?

Eunoe, Inc., the maker of COGNIShunt, is conducting additional clinical trials to assess the safety and effectiveness of the treatment and to test the hypothesis that the toxic factors in CSF contribute to the destruction of brain cells in Alzheimer's disease.

Additional research is needed to determine if surgery is a viable option for individuals with dementia. Any surgical procedure involves risks, which can be further complicated when an individual may have difficulty understanding those risks. Also, the risks of surgery need to be weighed against the potential long-term benefit of a procedure.

It is important for both the individual with Alzheimer's and family members to understand the conditions of an informed consent for participating in a clinical trial involving surgery.

The Alzheimer's Association is fighting on your behalf to give everyone a reason to hope. For more information about Alzheimer research, treatment and care, please contact the Alzheimer's Association.

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