

**Isidro Ferrer, M.D., Ph.D.**

**Center for Networked Biomedical Research on Neurodegenerative Diseases  
(CIBERNED)**

Barcelona, Spain

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## **Sativex in MCI Patients at High Risk of Developing Alzheimer's Disease**

*This Phase II clinical trial will examine if Sativex reduces brain inflammation and helps slow the progression of Alzheimer's disease in people with mild cognitive impairment*

### **Background**

Mild cognitive impairment (MCI) is a clinical condition in which brain function has declined, but not enough to impair activities of daily living. Certain types of MCI are associated with an increased risk of developing Alzheimer's disease in the future. Scientists are studying several ways to prevent the development of Alzheimer's disease in individuals with MCI who may have elevated risk. Reducing inflammation in the brain may be one potential way to help slow or prevent Alzheimer's progression.

Sativex® (nabiximols) is a cannabis-based liquid medication that is administered by spraying inside the mouth. It contains active ingredients called cannabinoids that are derived from the *Cannabis sativa* plant. These drugs interact with an extensive and complex nerve pathway in the brain known as the endocannabinoid system. Cannabinoids are believed to have anti-inflammatory and protective effects in the brain.

In animals with an Alzheimer's-like condition, Sativex reduced brain inflammation and improved cognitive function when given early in the disease process. In addition, Sativex has been approved in several European countries for treating certain symptoms of multiple sclerosis. Because information on the safety of Sativex in humans is already available, it may be possible to more quickly advance this medication to clinical trials for Alzheimer's disease.

### **Research Plan**

Isidro Ferrer, M.D., Ph.D., and colleagues have proposed a clinical trial of Sativex in people who have MCI and brain changes associated with a higher risk of developing Alzheimer's disease. The researchers plan to enroll 120 participants: 40 will receive three oral sprays of Sativex per day, 40 will receive 1 spray per day, and 40 will receive a placebo spray every day. All participants will be treated and monitored for 1 year. During that time, they will have their brain function tested and brain imaging performed. In addition, the researchers will obtain samples of blood and cerebrospinal

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fluid, which will be tested for markers of brain inflammation and Alzheimer's disease progression.

**Impact**

This Phase II proof of concept clinical trial will help determine if long-term use of Sativex can reduce brain inflammation in people with MCI, and potentially slow or prevent the development of Alzheimer's disease. The results of this work could lead to future large-scale trials of Sativex for the treatment of Alzheimer's disease.

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