

Alzheimer's-plagued Colombia region is focus of drug trial

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The unusually high incidence of early-onset Alzheimer's disease in this isolated cattle town has thrust it to the forefront of global efforts to find a cure for the debilitating malady.

Next spring, 100 residents of this region in northwestern Colombia who are known to carry a mutant gene linked to the disease will begin taking a [therapeutic drug](#) produced by the U.S. biotechnology firm Genentech. The five-year clinical trial, called the Alzheimer's Prevention Initiative, will cost \$100 million. The effort is backed by the U.S. National Institutes of Health and includes UCLA.

What sets this drug trial apart is that the patients, most of them in their 30s, will begin treatment long before they show symptoms of Alzheimer's. Researchers hope the drug will prevent its onset by blocking or slowing the formation of amyloid plaques in the brain that are associated with the devastating illness.

Because of a rare [genetic predisposition](#) among interrelated families, scores of residents here and in surrounding towns are getting Alzheimer's by their late 40s, about 15 years ahead of the norm. The cases can be traced to a "[founder effect](#)": a [common ancestor](#)'s "misspelled" gene, passed down over generations, that makes developing Alzheimer's a virtual certainty.

"It's a heavy burden for the relatives when the victims have to stop working and raising their children at such an early age," said Carlos

Orrego, administrator at San Juan de Dios Hospital, Yarumal's biggest. "For the families, the burden can last a very long time."

But the tragic circumstances also make this community an ideal place to test the Genentech drug, called crenezumab, which attacks beta amyloids and prevents them from becoming toxic.

Dr. Francisco Lopera, a co-manager of the trial and a neurologist at the University of Antioquia medical school in Medellin, 80 miles south of here, said it's the first test of its kind to be carried out on apparently healthy people. Lopera confirmed the genetic link to Alzheimer's cases here in the 1980s.

"Anti-amyloid drugs have been used before, but they have failed because they have been taken by patients already suffering from dementia - in other words, too late," Lopera said. "We are optimistic. We aren't sure it will prevent the disease, but it could delay it for many years, and that's important."

A hundred carriers of the mutant gene will take the drug over five years, and 100 carriers will take a placebo, as will 100 at-risk people who do not have the [mutant gene](#).

A "branch study" also will be conducted at UCLA's Geffen School of Medicine, where researchers have discovered a similar genetic disposition among members of an extended family from Jalisco state in Mexico. As many as 30 who have immigrated to Southern California could take part, neurology professor Dr. John Ringman said.

"It's an exciting and wise investment by the U.S. government in the cutting edge of Alzheimer's research," Ringman said. UCLA is looking for more at-risk patients to participate.

As many as 150 other U.S. patients who are Alzheimer's "mutation carriers" will take part in the trial at a dozen sites, said Dr. Eric Reiman of the Banner Alzheimer's Institute in Phoenix and a co-leader of the project. The inclusion of American patients is important so that Colombians don't feel exploited, he said.

"We think it's important to share benefits and risks with families in the United States," Reiman said.

The Alzheimer's Prevention Initiative is the "cornerstone of the U.S. government's national plan to attack Alzheimer's disease," he said.

The high-stakes research project reflects the growing health threat that Alzheimer's represents. An estimated 5.4 million Americans suffer from the disease, including 1 in 8 Americans older than 65. The percentage will grow in coming years as the population ages.

The cost of treatment and caregiving for Alzheimer's patients is soaring past \$200 billion a year, according to the Alzheimer's Association, providing ample incentive for the government to help find a cure.

To track the drug's progress in inhibiting plaques, patients will receive intravenous injections of a lightly radioactive imaging agent that will bind to amyloids floating in the fluid surrounding the brain. Patients will then undergo periodic brain scans to see whether the [amyloid plaques](#) are forming.

Genentech, which spent five years developing crenezumab, is shouldering \$65 million of the study's \$100 million cost. The NIH and the Banner Alzheimer's Institute are financing the balance.

Richard Scheller, an executive vice president of Genentech, said crenezumab has proved effective in blocking Alzheimer's-like symptoms

in laboratory mice.

The trial could also prove or disprove the hypothesis of many researchers that amyloids are at the root of Alzheimer's, which is still a mystery.

"[Amyloids](#) are the target," UCLA's Ringman said. "A guaranteed slam-dunk target? No. But it's the best we've got."

Said Scheller: "I've been a scientist a long time and sometimes complicated experiments don't work. But based on encouraging results so far, I'm cautiously optimistic we can help these folks."

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