

Second death in trial of experimental Alzheimer's drug is raising concerns

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Two people have now died from brain hemorrhages that may be linked

to an experimental Alzheimer's drug, calling into question the medication's safety.

A 65-year-old woman with early-stage Alzheimer's recently died from a massive brain bleed that some researchers link to lecanemab, an antibody drug designed to bind to and remove [amyloid-beta](#) from the brain, according to a report published Nov. 27 in *Science Insider*.

The woman suffered a stroke as well as a type of brain swelling and bleeding that has been previously seen with such antibodies, the report noted.

ER doctors at Northwestern University Medical Center in Chicago treated the woman with a common but powerful clot-busting drug, tissue plasminogen activator (tPA). She immediately had substantial bleeding throughout her brain's outer layer.

"As soon as they put it in her, it was like her body was on fire," her husband told *Science Insider*. "She was screaming, and it took like eight people to hold her down. It was horrific."

The woman died a few days later, the case report said.

The death follows that of an 80-year-old man who was taking part in lecanemab's phase 3 clinical trial. His death was linked to a possible interaction between the experimental drug and a blood thinner called apixaban (Eliquis).

Rudolph Castellani, a Northwestern neuropathologist who autopsied the woman, determined that she had [amyloid deposits](#) surrounding many of her brain's blood vessels.

The woman had been receiving biweekly infusions of lecanemab, which

appears to have inflamed and weakened her blood vessels, Castellani said. These vessels then burst when exposed to the clot-buster, something that can happen even in conventional stroke cases.

"It was a one-two punch," Castellani told *Science Insider*. "There's zero doubt in my mind that this is a treatment-caused illness and death. If the patient hadn't been on lecanemab, she would be alive today."

If approved, lecanemab would be the second anti-amyloid drug for Alzheimer's patients.

The first, Aduhelm (aducanumab), was approved by the U.S. Food and Drug Administration over the objections of reviewers and researchers who questioned the drug's effectiveness.

The Japanese firm Eisai Co. is scheduled this week to provide the first detailed account of lecanemab's phase 3 trial, which included about 1,800 people with signs of early Alzheimer's.

Eisai developed lecanemab with the Swedish firm BioArctic, and sponsored the clinical trial with U.S. biotech company Biogen.

A [news release](#) issued by the company in September said people taking lecanemab had less amyloid and 27% less [cognitive decline](#) than people who received a placebo during an 18-month period.

Eisai declined to comment on the woman's case, *Science Insider* said.

"All the available safety information indicates that lecanemab therapy is not associated with an increased risk of death overall or from any specific cause," the company said in a [statement](#).

The woman might have received either lecanemab or a placebo during

the 18-month trial, but she was definitely given the drug during the month preceding her death. She'd opted to receive it as part of an open-label extension of the clinical trial.

The woman and the man both had widespread cerebral amyloid angiopathy (CAA), a condition in which amyloid deposits gradually replace the smooth muscle of blood vessel walls.

Experts explained to *Science Insider* that in these types of patients, stripping the amyloid away—as drugs like lecanemab are meant to do—could weaken the [blood vessels](#) and make them vulnerable to bleeds if exposed to blood thinners or clot busters.

Nearly half of Alzheimer's patients have CAA, and many also suffer from heart ailments that are normally treated with blood thinners, the report noted.

More information: Second death linked to potential antibody treatment for Alzheimer's disease, *Science Insider* (2022). [DOI: 10.1126/science.adf9701](https://doi.org/10.1126/science.adf9701)

Mount Sinai has more about [cerebral amyloid angiopathy](#).

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