

New drug doesn't improve disability among stroke patients

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A new drug that showed promise in animal studies and an early clinical trial didn't improve disability among stroke patients, according to late-breaking research presented at the American Stroke Association's International Stroke Conference 2012.

After a stroke and other types of brain damage, the brain naturally produces more granulocyte colony stimulating factor (G-CSF). The protein can prevent further cell injury by protecting [nerve cells](#) and boosting [blood vessel growth](#).

The new drug, AX200, is a manufactured form of G-CSF.

Ninety days after treatment, patients receiving AX200 or a placebo both scored a three on the 0-6 modified Rankin scale, a common test for stroke-related disability.

In a secondary analysis, also at day 90, researchers assessed patients with the National Institutes of Health Stroke Scale. The difference between the drug and placebo was less than half a point (8.88 on AX200 vs. 8.45 on placebo), which was statistically insignificant.

"These top line results are disappointing and unexpected to us because AX200 showed signs of efficacy in a previous clinical trial with a limited number of patients, as well as in numerous animal studies," said Bernd Ringelstein, M.D., lead author of the study and Professor of [Neurology](#) at the University of Münster, Germany.

"At this time, we cannot speculate about their implications, but our current conclusion is that we were not able to show efficacy for AX200 as a treatment for acute ischemic stroke. We will have to analyze the complete data set in order to fully understand these results."

The study was conducted between August 2009 and November 2011 on 328 patients at 78 stroke treatment centers in eight European countries. The average age of the patients was 69 years and 52 percent were male.

Continuous intravenous infusion of AX200 began within nine hours of first symptoms and lasted for three days. Neither patients nor researchers knew which participants randomly received the drug or [placebo](#).

In the United States, stroke is the No. 4 killer and a primary cause of long-term disability among adults. The most common type, ischemic stroke, is caused by a blocked blood vessel to the brain.

Stroke warning signs are:

- Sudden numbness or weakness of the face, arm or leg, especially on one side of the body
- Sudden confusion, trouble speaking or understanding
- Sudden trouble seeing in one or both eyes
- Sudden trouble walking, dizziness, loss of balance or coordination
- Sudden severe headache with no known cause

If any of the symptoms occur, call 9-1-1 immediately, the American Stroke Association advises.

Provided by American Heart Association

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