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Spinal cord stem-cell trial could start soon, report says

A clinical trial that would test the use of embryonic stem cells to treat spinal cord injury could begin within three months.

The Scientist is reporting that the Food and Drug Administration (FDA) may lift its hold on a trial sponsored by California biotech Geron Corp. by early next year. In May, the agency ordered Geron to delay the trial while it studied how best to regulate stem-cell-based therapies.

The phase 1 trial would test whether it is safe to inject nerve cells into the site of a spinal cord injury. A study published in 2005 in the *Journal of Neuroscience* found that giving rats the injections seven days after a spinal cord injury improved their motor function.

Geron president and CEO Tom Okarma said there's no indication that politics were behind the FDA's delayed approval, according to *The Scientist*. He made his remarks at the New York Stem Cell Foundation conference at Rockefeller University last Wednesday.

President Bush banned federally funded research on embryonic stem cell lines created after Aug. 9, 2001. Democratic Presidential nominee Barack Obama told the group Science Debate 2008 that he would lift the limit, but John McCain, who has said he supports such research, has not made clear whether he would do so.

Among the concerns about stem cell therapy is whether it might cause cancer.

An FDA spokeswoman said the agency doesn't comment on products under development.
(Updated at 8:10 a.m. Tuesday with FDA response.)