

Japan approves stem-cell therapy for spinal cord injuries—but does it even work?

Japan has approved a stem-cell treatment for spinal-cord injuries. The event marks the first such therapy for this kind of injury to receive government approval for sale to patients.

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But independent researchers warn that the approval is premature. Ten specialists in stem-cell science or spinal-cord injuries, who were approached for comment by Nature and were not involved in the work or its commercialization, say that evidence that the treatment works is insufficient. Many of them say that the approval for the therapy, which is injected intravenously, was based on a small, poorly designed clinical trial.

They say that the trial's flaws — including that it was not double-blinded — make it difficult to assess the treatment's long-term efficacy, because it is hard to rule out whether patients might have recovered naturally.

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That the treatment won approval to be sold to patients is concerning, says James Guest, a neurosurgeon at the Miami Project to Cure Paralysis at the University of Miami in Florida. "This approval is an unfortunate step away from everything researchers have learned over the past 70 years about how to conduct a valid clinical trial," he says.

One of the inventors of the treatment, neurosurgeon Osamu Honmou of Sapporo Medical University in Japan, says he is preparing to publish a scientific paper that will discuss the clinical-trial and safety issues. "I think it is very safe."

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