island will return to nest once again.

Drones were chosen for the job because they are cheaper than a tried and tested tool — helicopters — but safer and easier than spreading the bait by hand on the extremely rugged terrain of the 184-hectare island.

On 12 January, a team using two six-rotor drones started spreading bait laced with rat poison around North Seymour island and the nearby islet of Mosquera. Each drone can carry up to 20 kilograms of bait for up to 15 minutes.

Mechanical difficulties with the drones shut the operation down when only half of North Seymour was treated, and workers had to spread the rest of the bait by hand — creating a natural experiment that could provide useful data on the drone approach. Island Conservation plans to compare outcomes in the drone-baited and hand-baited halves of the island.

The group intends to drop a second round of bait by drone in a few weeks. It will then monitor rat activity on the island for two years.

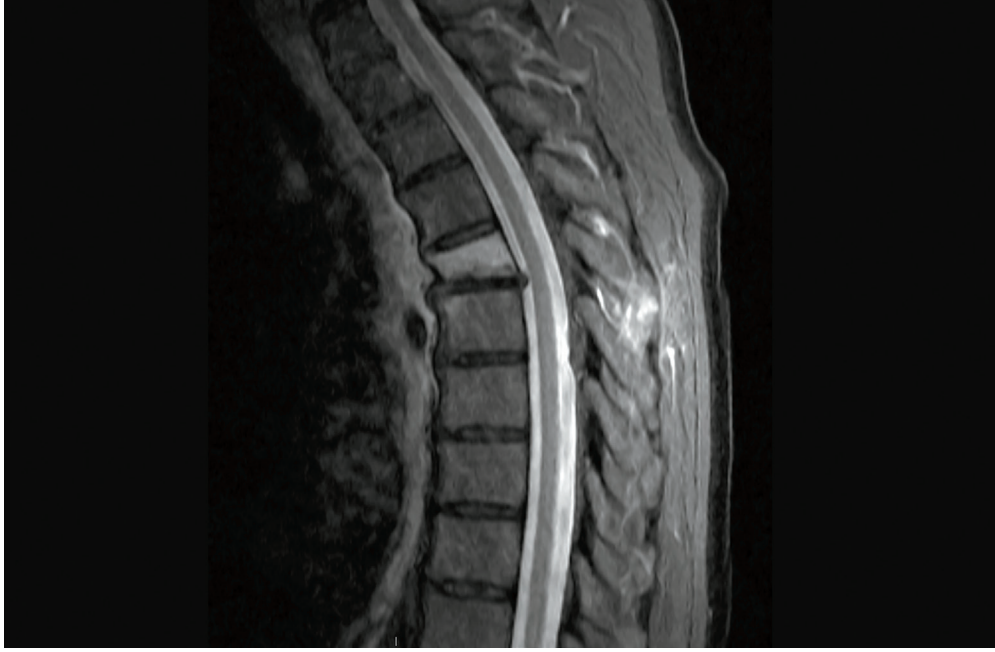
The project might be the first of its kind, but Campbell and others in the field expect drones to play an increasing part in culling non-native animals that threaten rare species. Especially on small, remote islands, far from helicopter companies, drones could be a much cheaper way to spread poison. Poisoning rats requires dropping bait twice, 21 days apart, Campbell says. "You have to have a helicopter for a month, sometimes shipped by boat. Your expenses very quickly add up."

Using drones for animal control is new, but conservation scientists are increasingly using the devices to monitor animals and ecosystems, and even to collect samples or spread seeds, says Serge Wich, a biologist at Liverpool John Moores University, UK, and a co-director of the Conservation Drones website, which follows the tool's rise in the field. "Almost every conservation organization I work with is using drones now, in one way or another," he says.

Craig Morley, an invasive-species specialist at the Toi Ohomai Institute of Technology in Rotorua, New Zealand, will be watching the Galapagos project closely. He is researching the use of modified drones to lay poison for Australian brush-tailed possums (*Trichosurus vulpecula*), which are considered pests in New Zealand because they eat the leaves and flowers of rare plants and snack on the chicks and eggs of native birds. New Zealand has set a goal of eliminating possums, rats and other predators from the country by 2050.

One advantage of using drones, Morley says, is that it reduces the need to cut trails through a forest to lay poison baits or traps.

But using drones to kill could also change how conservation scientists view such work, Morley says, comparing the approach to modern warfare. "You used to be able to see your opponent. Now, you just a press a button and you fire a missile," he says. "You become a little bit detached from the reality that you have killed something or somebody over there." ■



A stem-cell treatment for spinal-cord injuries will soon be available in Japan.

STEVEN NEEDELL/SPL

JAPAN

Stem-cell therapy raises concerns

Independent researchers warn that approval is premature.

BY DAVID CYRANOSKI

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

"This is an unprecedented revolution of science and medicine, which will open a new era of health care," says oncologist Masanori Fukushima, head of the Translational Research Informatics Center, a Japanese government organization in Kobe that has been giving advice and support to the project for more than a decade.

But 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 the approval is premature, because there is insufficient evidence that the treatment works. Many of them say 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 long-term efficacy, because it is hard to rule out whether patients might have recovered naturally. And, although the cells used — which are extracted from a patient's bone marrow and known as mesenchymal stem cells (MSCs) — are thought to be safe, the infusion of stem cells into the blood has been connected with dangerous blood clots in the lungs. And all medical procedures carry risks, which makes them hard to justify unless they are proven to offer a benefit.

"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," says James Guest, a neurosurgeon at the Miami Project to Cure Paralysis at the University of Miami in Florida.

One inventor of the treatment, neurosurgeon Osamu Honmou of Sapporo Medical University in Japan, says he plans to publish a scientific paper that will discuss the clinical-trial and safety issues. "I think it is very safe." He says he did not do a double-blinded study because Japan's regulations do not require it. "The most important point is that the efficacy is dramatic and definitive," adds Fukushima.

The unpublished results describe a trial of 13 people who had experienced spinal-cord injuries in the past 40 days. The team found that infusions of MSCs, which had been multiplied in the lab after they were extracted, helped the injured volunteers to regain some of the sensation and movement they had lost.

EARLY GREEN LIGHT

On the basis of these results, Japan's health ministry last month gave conditional approval for the treatment, called Stemirac. In the clinical trial, about 50 million to 200 million MSCs were intravenously infused back into patients 40 days after their injury to help repair the damage. The team can market and sell the therapy as long as they collect data from the participants over the next seven years that show that it works. People could start paying

for the treatment in the next few months.

Whereas many governments require new treatments to undergo rigorous clinical trials with hundreds of patients before the therapies can be sold, Japan has a programme to fast track the development of regenerative medicines: therapies need only show hints of efficacy, on the condition that the researchers collect follow-up data.

Honmou says that after 6 months, 12 of the 13 patients improved by at least one level on the internationally recognized American Spinal Injury Association impairment scale, which ranks people's ability to contract muscles and sense touch on various parts of the body.

The team thinks that the stem cells might repair spinal-cord damage by reducing inflammation and protecting existing neurons. The scientists also say that some of the infused stem cells develop into neurons that can replace damaged ones. Honmou says that he and others have demonstrated these mechanisms in animal studies[1].

The claim that MSCs can become neurons, in particular, concerns some of the independent scientists interviewed. Studies in the early to mid-2000s found that MSCs could take on certain features of neurons, such as expressing some of the same proteins[2,3], but the idea that they can function as neurons has been widely discarded.

So it is very unlikely that the MSCs converted to neurons in the trial, says Bruce Dobkin, a neurologist at the University of California, Los Angeles. Other studies in animals and people have found that MSCs infused intravenously tend to get stuck in the lungs. That makes it difficult to see how they can be effective in the spinal cord, says Pamela Robey, a stem-cell researcher at the US National Institutes of Health in Bethesda, Maryland.

"I do not think it is morally justified to charge patients for an unproven therapy that has risks."

Jeffery Kocsis, a neurologist at Yale University in New Haven, Connecticut, and a longtime collaborator of Honmou and others on the team, calls the results "potentially interesting", but says that "continued work will be necessary to fully substantiate efficacy".

The lack of double-blinding also raises concerns. This is a gold-standard method for assessing a treatment's efficacy, because neither physicians nor patients know who is receiving the experimental treatment. As a result, it reduces bias that could prevent scientists from discovering whether a treatment works, notes Guest. But in this case, the results could be explained by natural healing and physical rehabilitation in the months after an injury, says Dobkin. "This trial, as designed, cannot reveal efficacy," he says.

Fukushima says that the consistent improvement and high rate of success in their trial participants — even among those who were judged to have no hope of recovery — is "unprecedented". This could not have been achieved by natural healing with rehabilitation, he says.

Once the treatment is sold to patients, it will be even harder for the team to gather evidence that it is effective, says Arnold Kriegstein, a stem-cell researcher at the University of California, San Francisco. Paying for treatments can increase the likelihood that the patient will experience a placebo effect, and makes it impossible to perform a blinded trial, because people cannot be charged for a placebo procedure. Kriegstein also worries that the product could remain on the market without ever providing evidence that it works. "I do not think it is morally justified to charge patients for an unproven therapy that has risks," he says. ■ SEE EDITORIAL P.535

1. Inoue, M. *et al. Glia* **44**, 111–118 (2003).
2. Kim, S. *et al. Brain Res.* **1123**, 27–33 (2006).
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POLITICS

One US shutdown ends — but another looms

Government scientists are back at work after politicians approve three-week funding deal.

LAUREN MORELLO, AMY MAXMEN, ALEXANDRA WITZE, EMILIANO RODRÍGUEZ MEGA & JEFF TOLLEFSON

The US government reopened on 25 January after a historic 35-day shutdown that paralysed the National Science Foundation (NSF), NASA and other key science agencies. But any joy researchers felt was tempered by the knowledge that the government could shut down again on 16 February, when the current, temporary funding expires.

And even without another shutdown, it could take weeks or months for their agencies to return to normal operations.

"I'm a little nervous that we could be seeing this again in three weeks, but right now I am too happy to worry about it," says a fish biologist at the US Fish and Wildlife Service, who asked for anonymity to prevent retaliation by her agency. "We've been worrying for five weeks so it's just nice to take a break."

ALEX EDELMAN/GETTY

Congress has approved three weeks of funding.

The shutdown dragged on for two weeks longer than any other in US history, and its effects on science have been profound. It has interrupted studies of everything from California's coastal fisheries to clinical trials of experimental drugs, and key federal data sets have been pulled offline. Employees of many science agencies were forced to stay at home without pay for more than a month, and academic researchers have been deprived of key research funding.

Many government researchers returned to work on Monday 28 January — greeted, in some cases, by dead office plants, expired e-mail passwords or candy canes leftover from late December. Their agencies were scrambling to reschedule grant deadlines and review panels cancelled by the shutdown. NASA's associate administrator for science, Thomas Zurbuchen, said on Twitter on 24 January that the agency will delay consideration of new applications to one of its main research ▶