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At a press conference in Tokyo, cardiac surgeon Yoshiki Sawa announces plans to use tissue derived from induced pluripotent stem cells to treat heart disease.

CLINICAL RESEARCH

Reprogrammed stem cells approved to mend hearts

Japanese study is only the second application of induced pluripotent stem cells in people.

DAVID CYRANOSKI

Scientists in Japan now have permission to treat people who have heart disease with cells produced by a revolutionary reprogramming technique. The study is only the second clinical application of induced pluripotent stem (iPS) cells. These are created by inducing the cells of body tissues such as skin and blood to revert to an embryonic-like state, from which they can develop into other cell types.

On 16 May, Japan’s health ministry gave doctors the green light to take wafer-thin sheets of tissue derived from iPS cells and graft them onto diseased human hearts. The team, led by cardiac surgeon Yoshiki Sawa at Osaka University, says that the tissue sheets can help to regenerate the organ’s muscle when it becomes damaged, a symptom of heart disease that can be caused by a build-up of plaque or by a heart attack.

“It will excite worldwide attention, as many groups are working in the same direction,” says Thomas Eschenhagen, a pharmacologist at the University of Hamburg in Germany and chair of the German Centre for Cardiovascular Research.

The treatment will initially be given to three people over the next year. The team will then seek approval to conduct a clinical trial in around ten patients. If it proves safe, the treatment could then be sold commercially under Japan’s fast-track system for regenerative medicine.

The system, introduced in 2014, aims to speed the availability of potentially life-saving procedures. But critics say the system is flawed because it allows treatments to be on sale to patients before sufficient data have been collected showing that the procedures work.

MENDING BROKEN HEARTS

In their technique, Sawa and his colleagues use iPS cells to create a sheet of 100 million heart-muscle cells. From studies in pigs, the team has shown that grafting these sheets of cells — each 0.1 millimetres thick and 4 centimetres long — onto a heart can improve the organ’s function. Sawa says that the cells do not seem to integrate into the heart tissue. He thinks that instead they release growth factors that help to regenerate the damaged muscle.

Scientists say one advantage of the sheets is that they create their own cellular matrix, ▸

▶ and can maintain their structure without the need for scaffolding made from foreign materials, a feature of some other engineered tissues.

"It is a very elegant and clever way to deliver cells," says Philippe Menasché, a cardiac surgeon at the Georges Pompidou European Hospital in Paris, who has also experimented with making tissue sheets.

Pharmacologist Wolfram-Hubertus Zimmermann at the University Medical Centre Göttingen in Germany, who is also developing an iPS treatment for heart disease, says that the latest trial is based on work conducted by Sawa and other colleagues in Japan over the past 15 years.

Once Sawa's team has treated its three patients, it will apply to conduct a clinical trial involving a further seven to ten people. If the treatment proves to be safe, and shows some signs of working, it can be approved for sale under the accelerated system. This allows researchers to bypass expensive large-scale clinical trials aimed at proving efficacy, and instead to use small pilot trials to show that the therapy is safe and shows an indication of efficacy.

But some researchers say the bar for approving therapies for commercial use is too low. Even if the cells are found to be safe, there are risks associated with any surgery, and patients could give up other therapies for a treatment that might not work. Ethicists and regulators say the benefits of any new therapy must outweigh the risks.

Yoshiki Yui, a cardiologist at Kyoto University, says that, as well as meeting the requirements for safety, researchers should show that their treatment is effective, which would require testing it in larger numbers of people than are currently required. The evaluation process should also use randomized, controlled clinical trials, the gold standard for demonstrating efficacy in medical research, he says.

The iPS-cell therapy has potential, Yui adds, but under the current approval system, "we won't know if it works or not" because it won't have been tested in a controlled trial. "The biggest problem is there's no adequate system of evaluation in Japan," he says.

A spokesperson for the health ministry told *Nature* that the current approval system is sufficient because researchers must still show that a treatment works even if it has been approved for commercial use.

Sawa agrees that a control group is important for proving efficacy, but notes that he is abiding by Japan's rules, which don't require this before a treatment is made commercially available.

He says the health ministry's approval is an acknowledgement that the therapy "is scientifically and ethically justified" to be tested in patients. "Whether it really works, [we] have to find out now," he adds. ■ SEE EDITORIAL P.611

PHYSICS

Muography makes its mark

Little-known particles called muons are helping to map the insides of pyramids, and to spot missing nuclear waste.

BY ELIZABETH GIBNEY

The muon is going mainstream. The particle, a heavy version of the electron that constantly rains down on every square centimetre of Earth, is little known outside particle physics — but last year it helped archaeologists to make a stunning discovery of a previously unknown chamber in Egypt's Great Pyramid.

Volcanologists and nuclear engineers are also finding new uses for muography, which harnesses muons to probe the innards of dense structures. The first companies are looking to cash in.

"The discovery in the pyramids last year has really put muography on the map," says David Mahon, a physicist at the University of Glasgow, UK, who co-organized an international meeting called Cosmic-ray Muography, sponsored by the Royal Society and held on 14–15 May in Newport Pagnell, UK.

MUONS ARE EVERYWHERE

Muons have the same negative charge as electrons but 200 times the mass. They are made when high-energy particles called cosmic rays slam into atoms in Earth's atmosphere. Travelling at close to the speed of light, muons shower Earth from all angles. Every hand-sized area of the planet is hit by roughly one muon per second, and the particles can pass through hundreds of metres of solid material before they are absorbed.

Their omnipresence and penetrating power makes muons perfect for imaging large, dense objects without damaging them, says Cristina Cârloganu, a physicist at the Clermont-Ferrand Physics Laboratory in France. The denser materials are, the more energy they absorb from the particles, so physicists can track how often muons of different energies reach detectors placed around a target, and compare that with the expected rate without an obstacle, to build up a 3D profile of the density of the interior.

Physicists have been experimenting with the technique since the 1950s, including an unsuccessful search for hidden chambers in the second-largest pyramid at Giza (L. W. Alvarez *et al. Science* **167**, 832–839; 1970). But the room-sized detectors were expensive and impractical, says Raffaello D'Alessandro, a particle physicist at the University of Florence, Italy, and a co-organizer of the muography meeting. They could weigh more than 10 tonnes and relied on muons' ability to ionize particles of sometimes explosive gases.

CHANGE OF TACK

Ways to track the paths of charged particles more precisely — developed at facilities such as CERN, Europe's particle-physics laboratory near Geneva, Switzerland — have made for safer, smaller and more-sensitive muon detectors. They can now be as compact as a few square metres and can run on solar panels, making it possible to take them to remote field sites.

Volcanoes have become a popular target for the technique, thanks to pioneering work by researchers in Japan. Mapping lava channels, which absorb less energy from muons than does the dense surrounding rock, could one day help to predict eruptions, says Cârloganu. This year, researchers will try to image the solidified plug of lava inside Italy's Mount Vesuvius.

"It's a new, very specialist technique that comes from the high-energy-physics world."

Smaller devices are also being used in archaeology, says Giulio Saracino, a physicist at the University of Naples Federico II in Italy. He and his team have mapped cavities and tunnels under Mount Echia, a settlement in Naples that has been occupied since the eighth century BC. They also plan to look for a rumoured aqueduct beneath the nearby ancient city of Cumae.

A spate of commercial applications for muography — five were presented at the conference — probe smaller samples, such as drums of nuclear waste. These applications often use a slightly different technique, which tracks how muons change direction when they hit atomic nuclei in a material.

By placing detectors on both sides of a sample, physicists can recreate a particle's trajectory. And because the angle of deflection correlates with the density of the substance the muon hits, studying these paths can help to create a density map of the material being