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Japan sets safety standards for iPS cell transplants

TOKYO -- The Japanese health ministry has drawn up guidelines for determining the safety of laboratory-created stem cell treatments in clinical trials, a step that could pave the way for more such studies.

The standards, approved Friday, will be used to evaluate trials that involve transplanting induced pluripotent stem cells -- adult cells reprogrammed to a state similar to embryonic cells -- into the human body.

The safety standards call for testing these iPS cells for signs that they may turn cancerous. Ideally, only cells without cancer-causing abnormalities should be used, but exceptions may be made in cases where the potential benefits of the trial outweigh the risks, according to the guidelines.

The cells first would be transplanted into nonhuman subjects, such as rats, to check for cancer and other potential complications.

In 2014, Japanese researchers conducted the first clinical trial of an iPS cell treatment, transplanting tissue made of reprogrammed cells from a patient with a degenerative eye disease into the person's eyes. But a similar procedure on a second patient was called off after genetic abnormalities were found in the iPS cells created for that person. These abnormalities did not affect genes linked to cancer.

This experience helped underscore the need for guidance on what should be tested, and to what extent, before iPS cell treatments can be deemed safe. Now, with standards in place, "our work has become easier," said Masayo Takahashi, project leader for retinal regeneration at Japan's government-backed Riken research institute.

"We expect that going forward, work on medical applications of iPS cells will accelerate further," Nobel Prize-winning stem cell researcher Shinya Yamanaka, director of the Center for iPS Cell Research and Application at Kyoto University, said in a statement.

The research team that devised the standards was led by Tsuguya Fukui, president of St. Luke's International Hospital in Tokyo.

(Nikkei)

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