

〈講 演〉

第 42 回日本香粧品学会 (2017) ・特別講演Ⅱ

iPS 細胞による加齢黄斑変性治療

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Treatment for Age-Related Macular Degeneration Using iPS Cells

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Abstract

The first in man application of iPS-derived cells started in September 2014 targeted the retinal disease called age-related macular degeneration (AMD). AMD is caused by the senescence of a layer of the retina called retinal pigment epithelium (RPE). It is the major cause of visual impairment in advanced countries. We aim to develop a treatment that replace damaged RPE with normal, young RPE made from patients' own iPS cells to rescue photoreceptors in the neural retina. In the clinical study, we generated iPS cells from patient's skin fibroblast. RPE cells were differentiated from iPS cells. Picking up the brown cluster of cells, hiPS-RPE cells were purified. Cells were evaluated their purity, function, various genetic examination and tumorigenicity test using mice to check the safety. We judged the outcome 1 year after the surgery. Primary end-point; the safety was successfully achieved in the first case as we expected. However, autologous transplantation is time consuming and the cost is high. It is necessary to prepare allogeneic transplantation to establish a standard treatment. RPE cells are suitable for allogeneic transplantation because they suppress the immunoreaction and it is possible that the rejection is considerably little if we use the HLA matched iPS cell. After we confirmed that HLA matched iPSC-derived RPE show no immune rejection in model animals, we announced the new clinical research using allogeneic transplantation of iPSC-derived RPE. In Japan pharmaceutical law has been changed and a new chapter for regenerative medicine was established. This is the first law specific for regenerative medicine in the world. It was determined in the co-operation with ministry & academia and its success will depend on the co-operation of regulatory authorities, academia and companies.

Key words: age-related macular degeneration, iPS cells, regenerative medicine, retinal pigment epithelial cell, primary end point.