

Research Center for Medical Sciences GMP Production Facilities for Cell Therapy and Gene Therapy

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General Summary

Clinical trials

A Good Manufacturing Practice-grade Cell Processing Factory has been operating for a long time in the Research Center for Medical Sciences. Until now, middle ear mucosa regeneration by grafting artificial mucosa for intractable middle ear disease by otolaryngology, and clinical trials of immune cell therapy for brain tumors by neurosurgery and pediatrics have been performed. Middle ear mucosa regeneration by grafting artificial mucosa has been adopted by the Japan Agency for Medical Research and Development (AMED) as a research project for practical application of regenerative medicine and is currently undergoing nonclinical safety tests. Immune cell therapy for brain tumors has been safely performed by neurosurgery and pediatrics this year, and cases are accumulating. We are aiming to be included in a AMED practical research project for innovative cancer medical treatment.

Opening of a new Cell Processing Factory in 2020

The new outpatient building of 2020 will include a cell processing facility that applies the concept of manufacturing control and the quality control standards of Good Manufacturing Practice/Good Gene, Cellular, and Tissue-based Products Manufacturing Practice Ministerial Ordinance. We believe that our mission is to perform the first clinical trials in human patients and investigator-initiated clinical trials developed from academia seeds. We would like to focus on the findings and problems that can be discovered for the first time in clinical research during this exploration period and connect them to the period of development. On the other hand, the Cell Processing Factory will also play roles in such hospital functions as storage, in the quality control of such cell processing products as chimera antigen receptor T cells, and in regenerative medicine. Making the most of the benefits of the region, we will also aim to support and revitalize research in cancer immunotherapy and regenerative medicine through industry-academia collaboration.

Research Activities

Department of Neurosurgery (Yasuharu Akasaki)

We are conducting clinical studies of immunotherapy for malignant glioma using tumor cells and cells fusing tumorigenic cells and dendritic cells. This is a study of immunotherapy using dendritic cells, known as specialized antigen-presenting cells, fused with tumor

cells as a tumor vaccine. Furthermore, the fused cells are activated by polyinosinic: polycytidylic acid/interleukin 10-short interfering RNA-embedded cationic liposomes to promote secretion of endogenous interleukin 12.

Department of Pediatrics (Masayoshi Yamaoka)

We are conducting autologous dendritic cell therapy for refractory pediatric brain tumors jointly by pediatrics and neurosurgery. In 2019 cell therapy was performed 12 times for 4 children with brain tumors. No adverse events were observed in any patient, and the effects of therapy could be confirmed in all 4 patients. Relapse-free survival occurred in 2 patients; tumors recurred in 2 patients, but the recurrence pattern was changed and 1 patient was in remission after undergoing a second operation. We will continue to accumulate cases and report at the International Society for Childhood Brain Tumors held in December 2020.