

GMP Production Facilities for Cell Therapy and Gene Therapy

Sadamu Homma, *Professor and Director*

Tomoko Ohmae, *Assistant Professor*

General Summary

This facility was established for clinical studies based on cell therapy, gene therapy, and regenerative medicine. Cell products are generated here on the standard of Good Manufacturing Practice (GMP) for safe administration to the patients in clinical studies. Specified regulation and education have been performed strictly for the maintenance of the GMP standard in this facility.

Research Activities

Regenerative medicine for prevention of hearing impairment after the operation for pearl tumor in the ear

Hearing impairment after the surgical treatment for pearl tumor is often induced by the adhesion of auditory ossicles in the ear. To prevent adhesion of auditory ossicles, sheets of autologous nasal cells are to be attached on the surface of auditory ossicles during the operation. Several patients have received this treatment in operations for pearl tumors, and the preventative effect on hearing impairment is now being examined.

Immunotherapy with dendritic cell vaccine against glioblastoma

The combination therapy with temozolomide and dendritic cell vaccine therapy against glioblastoma was performed. Patients with glioblastoma were assigned to 2 groups: a group with recurrent glioblastoma after failing temozolomide chemotherapy or a group with newly diagnosed glioblastoma. Autologous cultured glioma cells obtained from surgical specimens were fused with dendritic cells using polyethylene glycol treatment. Both progression-free survival and overall survival in patients with recurrent glioblastoma (n = 9) or newly diagnosed glioblastoma (n = 20) were significantly longer in patients who received immunotherapy than in control patients who did not.

Combined treatment with Wilms' tumor 1 peptide-pulsed dendritic cells and the anticancer drugs against advanced pancreatic cancer

Combined treatment was performed with dendritic cells pulsed with Wilms' tumor 1 peptide, both HLA classes I and II restricted antigenic peptides, and anticancer drugs, mainly gemcitabine or S-1, against advanced pancreatic cancer. Because a female patient has survived longer than 2 years in good physical condition, her dendritic cells were generated periodically from the peripheral blood mononuclear cells in this facility.

Publications

Koido S, Homma S, Okamoto M, Takakura K, Mori M, Yoshizaki S, Tsukinaga S, Odahara S, Koyama S, Imazu H, Uchiyama K, Kajihara M, Arakawa H, Misawa T, Toyama Y, Yanagisawa S, Ikegami M, Kan S, Hayashi K, Komita H, Kamata Y, Ito M, Ishidao T, Yusa S, Shimo-

daira S, Gong J, Sugiyama H, Ohkusa T, Tajiri H. Treatment with chemotherapy and dendritic cells pulsed with multiple Wilms' tumor gene 1(WT1)-specific MHC class I/II-restricted epitopes for pancreatic cancer. *Clin Cancer Res.* 2014; **20**: 4228-39.