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# Clinical Trial of Allogeneic Mesenchymal Stem Cell Therapy for Chronic Active Antibody-Mediated Rejection in Kidney Transplant Recipients

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**Objectives:** The aim of this study is to investigate the therapeutic effect of allogenic mesenchymal stem cell therapy (MSC) in kidney transplant recipients (KTR) diagnosed with chronic active antibody-mediated rejection (CAMR).

**Methods:** A total of 5 patients diagnosed with CAMR by allograft biopsy were enrolled. Each patient received MSC for 4 cycles ($1\times10^6$ cells/kg every other week) via peripheral vein. Human bone marrow-derived MSC (Catholic MASTER Cells) were obtained from the Catholic Institute of Cell Therapy (CIC, Seoul, Korea). The Catholic MASTER Cells were certified by the KFDA.
Blood samples were collected at baseline and 1, 3, and 6 months after the end of treatment. Routine blood chemistry tests including serum creatinine, third party donor-specific Elispot and lymphocyte subsets analysis were performed using blood samples.

**Results:** Of the total of 5 patients, 2 patients maintained their allograft function well during the follow-up period. Two of the three patients who experienced graft loss started hemodialysis. The other patient developed Pneumocystis jirovecii pneumonia (PJP) 5 weeks after treatment, and expired on Week 6. There were no infectious complications other than PJP, and there were no serious adverse events related to MSC administration. A significant decrease in HLA antibody titer was observed in all patients after the MSC administration.
In the flow cytometry results, CD8+CCR7+ T cells and CD8+CCR7-CD45RA- T cells decreased after MSC administration. CD4+CD161+ T cells, CD4+CD25+CD127low T cells and CD8+CCR7-CD45RA+ T cells showed a conversely increasing trend.
There was no significant difference in renal function and allograft survival between the MSC treated patients and the historical control group treated with rituximab. It was observed that the incidence of infectious adverse event was lower in the MSC group.

**Conclusions:** MSC showed the comparable therapeutic effect with rituximab on CAMR with lower risk of infectious adverse events. Further lager scale studies are required with the MSC.