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Phase I/II study of vaccination with immature and mature dendritic cells in patients with melanoma and renal cell carcinoma

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Dendritic Cells (DC) may influence the development of a natural immune response and could be potentially effective in specific treatments for cancer patients. A phase I-II vaccination trial for patients with advanced melanoma and renal cell carcinoma (RCC) is ongoing in our Department of Oncology. In the present study we compared the therapeutic use of intradermally administered immature DC (iDC) and mature DC (mDC) pulsed with autologous tumor lysate (ATL) and keyhole limpet hemocyanin (KLH). iDC were differentiated from adherent PBMC obtained by leukapheresis and cultured with IL-4 (1000 IU/ml) and GM-CSF (1000 IU/ml) for 6 days. ATL and KLH were added on the 6th day. On the 7th day iDC were used for therapeutic infusion in 9 patients, while mDC, obtained after a further 48-hour stimulation with IL-1β, IL-6, TNFα and PGE2, were administered in 10 successive patients. Treatment schedule was as follows: vaccination on days 0 and 16, and once a month thereafter for at least 5 cycles or until progression occurred. Patients received IL-2 subcutaneously at a dose of 3,000,000 IU/die from days 2 to 6 of each cycle. Of the 9 patients (8 melanoma and 1 RCC) treated with iDC, 4 showed stable disease (SD) of 19, 6, 6, and 6 months' duration, and 5 progressed. Four of these patients also had weak delayed-type hypersensitivity (DTH) skin reactions for KLH or ATL. The 10 patients (9 melanoma and 1 RCC) treated with mDC obtained the following results: 1 complete response (abdominal lymph nodes) of 10+ months' duration, with positive DTH for both ATL and KLH and onset of vitiligo, 1 partial response (lung and lymph nodes) of 3 months' duration, with subsequent development of brain metastases, 1 mixed response (skin and lymph nodes) lasting 6 months with positive DTH for both ATL and KLH and subsequent development of brain metastases, 3 SD of 9 (RCC patient), 9 and 7+ months' duration with positive DTH only for KLH (one patient progressed with brain metastases). Four patients with negative DTH for ATL progressed (1 brain metastases). mDC vaccination appears to be more effective in inducing clinical and immunological responses than iDC. In particular, 2 responder patients showed evidence of an immunological response that was specific for ATL. The disease would seem to have a high propensity to spread to the Central Nervous System, and a form of protection with liposoluble chemotherapy could therefore be hypothesized in future.

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