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Dendritic cell-based immunotherapy of hormone refractory prostate carcinoma (HRPCa) – a pilot trial

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Rationale

Prostate cancer is one of the most common cancer found in man. For patients with hormone-refractory, metastatic tumour no effective therapy is available and prognosis is very poor. Therefore we designed a clinical study using a novel approach for the treatment of patients with advanced stages of prostate cancer. Preliminary data concerning dendritic cell (DC) based vaccination revealed promising results but the clinical relevance is still questioned. Thus, we decided to develop a clinical protocol for the treatment of 12 patients with hormone-refractory prostate carcinoma using prostate-specific antigen (PSA)-derived peptides loaded on DC.

Methods

PBMC from HLA-A2 positive patients are isolated from the peripheral blood by Leucapheresis. Monocytes are seperated by adherence and differentiated into immature DC by incubation with GM-CSF and IL-4 under serumfree conditions over six days. Then DC are matured with TNF-α and PGE_2 and pulsed with three different PSA-Peptides (PSA-1 [FLTPKKLQCV]; PSA-2 [KLQCVDLHV]; PSA-3 [VISNDVCAQV]). For vaccination 6×10^6 Peptide-pulsed DC are applied intracutaneously after previous subcutaneous application of INF-γ (50 μg/m^2). Vaccination is performed 4 times in 3 week intervals. Patients are included after informed consent and sufficient hematological liver and renal function. Primary end point of the trial is the evaluation of PSA, measurable tumour parameter after 4 vaccinations and clinical benefit. Secondary end points are safety, quality of life (EORTC-QLQ-C30) and immunological parameters.

Results

Until now 8 patients are enrolled. 4 patients completed all 4 scheduled vaccination. 3 patients are still under vaccination. One patient dropped out due to early progress. The vaccination is well tolerated without any therapy related adverse event. Response rates are under evaluation and will be presented.

Conclusion

Vaccination with PSA-peptide-pulsed autologous DC combined with INF-γ is feasible and well tolerated. Further evaluation is in progress.