Unveiling the immunological landscape of resected stage III/IV Melanoma patients treated with personalized dendritic cells vaccination in a phase II randomized trial. #P508

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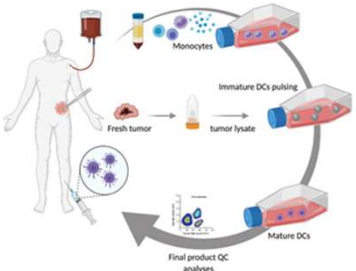


DCs vaccine manufacturing process

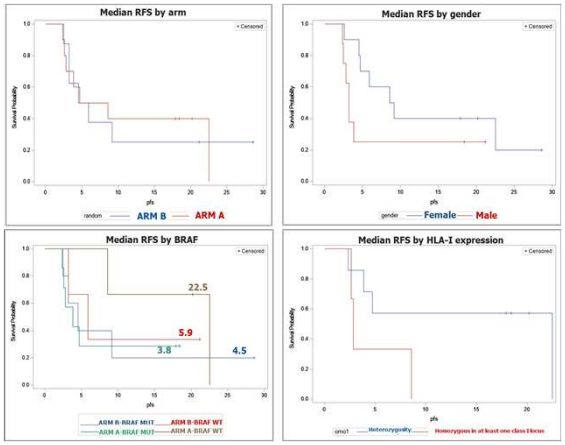
Randomized Phase II study in radically resected stage III and IV melanoma§

Treatment arm (DC-Arm)
6 vaccines every 4 weeks
(followed by IL-2 3 MU/day for 5 days)

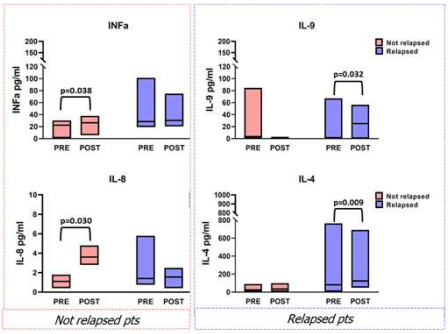
Follow up (FU-Arm)

§The study was closed because no longer ethical after the introduction in the clinical practice of new drugs in the adjuvant setting of melanoma

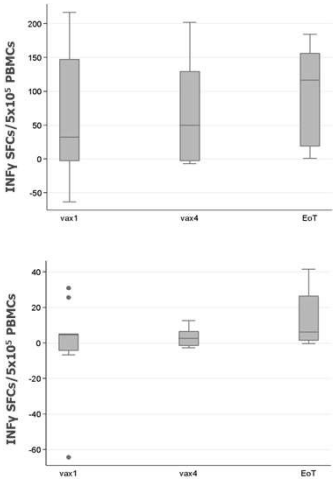
Results



DC vaccine confers the best RFS to young female patients with BRAF WT status and the heterozygosity profile of HLA class I loci. Median RFS (in months) has been calculated by treatment arm (Arm A=6.6; Arm B=5.2), by age (not shown, < 60 years= 14.2; ≥ 60 years= 4.6), by gender (female pts= 8.9; male pts= 3.2), by BRAF status (Arm A and BRAF WT=22.5; Arm A and BRAF MUT= 3.8; Arm B and BRAF WT= 5.9; Arm B and BRAF MUT= 4.5) and by HLA-I typing



Significant Immune modulation at the periphery seems related to DC vaccination clinical outcome



CONCLUSIONS

In our study the melanoma DC-vaccinated pts have shown the better RFS compared to whose randomized in the observational cohort. Although the number of enrolled pts as limited the extension of our investigation a special correlation was observed with RFS and female gender, age under 60, WT BRAF status and HLA-I loci heterozygosity.

The DC vaccine was able to elicit a specific immunological response against TAAs expressed in melanoma, increasing after therapy the frequency of specific INFγ secreting T cells.

A fine tune periphery immunomodulation was observed in not relapsed (NR) vaccinated pts with an increment of pro-inflammatory cytokines (INFa and IL-8) and of effector memory and terminal effector subsets CD4+ T cells.

An increased number of specific anti-survivin and anti-NY-ESO1 spot forming cells (SFCs) was observed along DC vaccine

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