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POSTER PRESENTATION Open Access

Phase I/II study of Resiquimod as an immunologic adjuvant for NY-ESO-1 protein vaccination in patients with melanoma

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Purpose

The TLR 7/8 agonist, Resiquimod has been shown to induce local activation of immune cells, production of cytokines, and antigen-presentation by dendritic cells, features desirable for cancer vaccine adjuvants. In this study, we evaluated the safety and immunogenicity of vaccination with NY-ESO-1 protein emulsified in Montanide ISA-51 VG when given with or without Resiquimod in surgically resected stage IIB-IV melanoma patients.

Experimental design

This is a two-part study design. Part I represents an open-label dose-escalation with Resiquimod using 2 cohorts treated with 100μg NY-ESO-1 protein emulsified in 1.25mL Montanide (day1) followed by topical application of 1000mg of the 0.2% Resiquimod gel on days 1 and 3 for cohort-1 (N=3) or days 1, 3, and 5 for cohort-2 (N=3). The cycles were repeated every 3 weeks, total of 4 cycles. For part II of the study, patients were blindly randomized to receive 100μg NY-ESO-1 protein emulsified in 1.25mL Montanide (day1) followed by topical application of placebo gel (Arm-A; N=8) or 1000mg of 0.2% Resiquimod gel (Arm-B; N=12) using the dosing regimen established in Part I. Blood samples were collected at baseline, one week after each cycle of vaccination, and at follow-up visit for the assessment of NY-ESO-1-specific humoral and cellular immune responses.

Results

The vaccines were generally well-tolerated, with no grade 4 adverse events or study-related deaths. Most study participants experienced mild adverse reactions reported as Grade 1 or 2 per CTCAE criteria v. 4. One patient experienced a grade 3 syncopal episode that was unrelated to the study drugs and another patient had a grade 3 injection site necrosis that was possibly related to the study drugs. NY-ESO-1 specific antibody responses were induced in both study arms although higher mean antibody titers were observed in Arm B. NY-ESO-1 specific CD4+ T cell responses were induced in patients in both study arms. However, significant NY-ESO-1 CD8+ T cell responses were detected only in Arm B.

Conclusions

The current study shows that Resiquimod is safe and contributes to the induction of immune responses in patients.

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