immunotherapy of cancer

RACOTUMOMAB-ALUM VACCINE FOR MAINTENANCE TREATMENT OF RECURRENT PLATINUM-SENSITIVE EPITHELIAL OVARIAN CANCER PATIENTS

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Background: Epithelial ovarian cancer (EOC) is the leading cause of death from gynecologic cancer. Around 75% of the patients are in advanced clinical stages at diagnosis. Despite improvements in cytoreductive surgery and primary chemotherapy over 80% of advanced stage patients will relapse. Racotumomab-alum is a therapeutic cancer vaccine composed by a murine monoclonal antibody (racotumomab) and alum as adjuvant. It is able to induce a specific antibody response against N-glycolilGM3 tumor associated antigen. Its antitumoral activity has been demonstrated in melanoma, breast cancer and NSCLC. The aim of this clinical trial is to evaluate the efficacy and safety of racotumomab-alum as maintenance treatment for recurrent platinum-sensitive EOC.

Trial design: This phase II/III multicenter, controlled clinical trial will include 88 patients with histologically confirmed EOC, clinical stage II-IV, with two prior platinum-based chemotherapy treatments and objective response after last regimen, with ECOG performance status 0-2, that signed informed consent, with normal renal, hematologic and hepatic functions. Will be excluded patients with prior treatment with racotumomab-alum or any investigational drug, platinum-resistant disease, pregnancy or breast feeding, history of brain metastasis or spinal cord compression, uncontrolled chronic diseases, previous adverse reactions to vaccines, history of immunodeficiency or autoimmune disease. Patients will be randomized with 1:1 ratio to receive racotumomab-alum or best supportive care. The primary endpoint will be progression free survival (PFS) and we will also evaluate OS, Safety, and Immunological response. The NGcGM3 expression in tumor samples and immunophenotype of tumor infiltrating cells will be evaluated to correlate with clinical endpoints. Racotumomab-alum treatment consist in 5 biweekly intradermal doses (induction phase) followed by monthly re-immunization (maintenance phase) until unacceptable toxicity or PS worsening. Treatment will not be stopped at progressive disease; other chemotherapy lines will be given concomitantly. We have hypothesized a 4 months advantage in PFS for vaccinated group.

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