Study Title	**A Phase II Study of (IGFBP-2) Vaccine to Prevent Progression after Serologic Detection of Recurrent Ovarian Cancer**
Study Population	Platinum pretreated ovarian, fallopian tube and primary peritoneal cancer patients who have received and responded to front-line systemic chemotherapy with platinum-based chemotherapy and are without radiographic evidence of disease but in whom CA-125 is increasing will be eligible to enroll.
Study Design	This will be a phase II, single treatment arm study. The treatment regimen comprises a single dose of carboplatin and a series of three IGFBP-2 vaccinations, administered at intervals of four weeks each. The study will enroll 22 patients.
Key Eligibility Criteria	1. Have a diagnosis of ovarian, fallopian tube, or primary peritoneal cancer who have received systemic chemotherapy including platinum-based chemotherapy. 2. Have a CA-125 that normalized after first-line therapy. 3. CA-125 increased to more than twice the upper limit of normal or two times the nadir value after most recent second or later line of treatment. 4. Have no measurable disease based on RECIST 1.1. Ascites and pleural effusions are not measurable disease, if asymptomatic 5. Have a performance status of 0 or 1 on the ECOG Performance Scale 6. Adequate Laboratory values. 7. Is not receiving systemic steroid therapy. 8. Cannot have known central nervous system (CNS) metastases and/or carcinomatous meningitis. 9. Cannot have active autoimmune disease that has required systemic treatment in the past 2 years.
Study Treatment	All patients will receive the IGFBP-2 vaccine admixed with GM-CSF (as an adjuvant) after receiving a single dose of carboplatin. • Single carboplatin infusion will be administered (per standard of care) by the patient's primary oncologist 2-3 days prior to first study vaccine (Carboplatin IV, AUC 6). • The dose of IGFBP-2 that will be used for this trial will be 100 mcg admixed with 100 mcg GM-CSF and given intradermally in 3 injections per dose. ○ The IGFBP-2 vaccine will be administered every 4 weeks (+7 days) for a total of 3 vaccines Patients will then be evaluated 1 month after Vaccine #3, 6 months after Vaccine #1 for an End of Treatment (EOT) visit and every 3 months after Vaccine #3 for up to 1 year for radiographic evidence of recurrence of disease. Clinical labs will be collected prior to Vaccine #1, Vaccines #1, #2 and #3, 1 month post Vaccine #3 and EOT. In addition, we will perform IGFBP-2 serology. We will also collect CA125 approximately every 4 weeks for up to 1 year. Research blood draws for immune monitoring will occur: (1) prior to Vaccine #1, (2) 1-month post Vaccine #3 and (3) 6 months after Vaccine #1 (EOT).
More Information	• NCT#: [Insert NCT#] • www.uwcvi.org
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