

Study Title	EWOC-1 Multicenter, randomized trial of carboplatin +/- paclitaxel in vulnerable elderly patients with stage III-IV advanced ovarian cancer.
Primary Objective	<p>To evaluate the success rate of 3 different chemotherapy regimens in women > 70 with ovarian cancer stage III-IV, considered as vulnerable upon defined Geriatric Vulnerability Score (GVS). Success is defined as the ability to deliver to patients 6 courses of chemotherapy without premature termination for progression, death or unacceptable toxicity. Patients will be randomised to receive 6 courses of one of the 3 following regimens:</p> <ul style="list-style-type: none"> - Arm A: Paclitaxel 175 mg/m²/3 hours, I.V. and carboplatin AUC 5, I.V. every 3 weeks, - Arm B: Carboplatin monotherapy AUC 5 or 6 every 3 weeks, - Arm C: Weekly paclitaxel 60 mg/m²/1 hour and weekly carboplatin AUC 2 (d1,d8, d15 every 4 weeks).
Secondary Objectives	<ul style="list-style-type: none"> • Therapeutical strategy (feasibility of performing an optimal surgery and feasibility of performing neoadjuvant chemotherapy and surgery and post operative chemotherapy until 6 courses); • Interval debulking feasibility; • Post-operative chemotherapy feasibility; • Progression-free Survival (PFS); • Overall Survival (OS); • Quality of life (QOL); • Safety and tolerability; • Geriatric covariates and patient out come. <p>Exploratory objective Aging biomarkers and patient outcome</p>
Inclusion Criteria	<ul style="list-style-type: none"> • Woman >70 year old: a patient can be included the day after her 70th Birthday; • Histologically or cytologically proven FIGO stage III to IV epithelial ovarian cancer or peritoneal primary or fallopian tube. A cytological proof is accepted if associated with a ratio of CA125/CEA >25 and a radiological pelvic mass. • GVS (Geriatric Vulnerability Score) >3. • Adequate bone marrow function including the following: Neutrophils $\geq 1.5 \times 10^9/L$, platelets $\geq 100 \times 10^9/L$ and hemoglobin ≥ 9 g/dL. • Adequate glomerular filtration rate >40 ml/min (estimates based on MDRD or CKD-EPI formula are sufficient) • No icterus. • Life expectancy > 3 months. • Written informed consent obtained. • Covered by a Health System where applicable.

<p>Exclusion Criteria</p>	<ul style="list-style-type: none"> • Other malignancy within the last 5 years, except for adequately treated carcinoma in situ of the cervix or squamous carcinoma of the skin, or adequately controlled limited basal cell skin cancer; • Prior history of chemotherapy for the present malignancy; • Prior history of radiotherapy which may affect patient tolerability to chemotherapy; • Major perturbations of liver biology: Bilirubin > 2 fold the upper normal limit (UNL), SGOT-SGPT > 3 fold UNL; • Patient unable to be regularly followed for any reason (geographic, familial, social, psychologic); • Any mental or physical handicap at risk of interfering with the appropriate treatment; • Known allergy to Cremophor R EL -containing drugs; • Any administrative or legal supervision where applicable
<p>Number of Patients to enroll</p>	<p>120/240 patients to randomize Suspension of randomizations on 28.04.2017</p>

For Information

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