

GOG 0256: A PROSPECTIVE STUDY OF COGNITIVE FUNCTION DURING CHEMOTHERAPY FOR FRONT-LINE TREATMENT IN OVARIAN, PRIMARY PERITONEAL OR FALLOPIAN TUBE CANCER

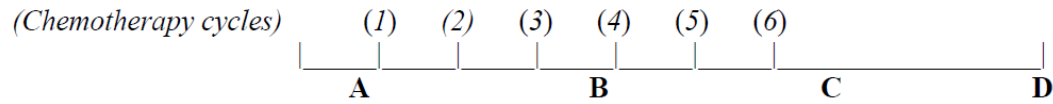
Fast Facts

Eligible Patients

1. Patients who have a histologically or pathologically confirmed primary diagnosis of Stage I-IV ovarian, primary peritoneal, or fallopian tube cancer (any cell type).
2. Patients who have met the pre-entry requirements specified in Section 7.0.
3. Patients must be able to comply with all aspects of the study, be able to read and understand English, and must have signed an IRB approved informed consent and authorization permitting release of personal health information.
4. Patients who are prescribed a minimum of 6 courses of chemotherapy (for example, patients with early-stage disease who will only receive 3 courses of therapy are not eligible, but those with early-stage disease who will receive 6 courses are eligible).
5. Patients with GOG Performance Grade of 0, 1 or 2.
6. Patients who have not yet received the first course of prescribed chemotherapy.
7. Patients must be female ≥ 18 years of age.

Ineligible Patients

1. Patients with GOG Performance Grade of 3 or 4.
2. Patients with a history of other invasive malignancies, with the exception of non-melanoma skin cancer, are excluded if there is any evidence of other malignancy being present within the last five years.
3. Patients who have received prior radiotherapy or chemotherapy.
4. Patients who have uncontrolled or severe cardiovascular disease, including recent (<1 year) myocardial infarction, uncontrolled hypertension, or congestive heart failure.
5. Patients who have a history of head injury with GCS < 13.
6. Patients who have had treatment within the previous 6 months with epoetin alfa, darbepoetin, or any investigational forms of erythropoietin. However, these agents are allowable during chemotherapy treatment as needed.
7. Patients who have severe hemiparesis or other condition preventing bimanual keyboard operation.
8. Patients who have distal neuropathy, action tremor, or other motor dysfunction that would substantially decrease keyboard accuracy.
9. Patients who have severe motor or mental slowing (patient who is disoriented/level C on any criterion as assessed by the person-place-time criteria, Appendix I).
10. Patients whose circumstances at the time of study entry do not permit completion of the study or required follow-up.

SCHEMA**KEY:**

A-Visit 1: Up to five days prior to receiving cycle 1 of chemotherapy
 Enrollment, Baseline Neurocognitive Evaluation (Patient Assessment and Own Functioning Scale (PAF), Headminder Custom Research Tool (CRT), and Quality of life (QOL) assessment (HADS, FACT-O, and FACT/GOG-Ntx subscale)

B-Visit 2: Up to five days prior to receiving cycle 4 of chemotherapy
 PAF, Headminder CRT and QOL

C-Visit 3: Three weeks (+/- 1 week) after cycle 6 of chemotherapy
 PAF, Headminder CRT and QOL

D-Visit 4: Six months (+/- 2 weeks) post cycle 6 of chemotherapy therapy
 PAF, Headminder CRT and QOL