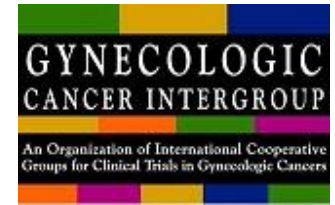




New Concept



GOG 3021

A Phase II Trial of Doxorubicin Combined with Olaratumab in the Treatment of Recurrent or Persistent Carcinosarcoma of the Uterus or Ovary

Number of study subjects: 20-38

Estimated duration: 20-24 months if study goes to second stage

Primary objective: To assess the activity of doxorubicin plus olaratumab in patients with persistent or recurrent carcinosarcoma of the uterus or ovary as measured by the proportion of patients who survive progression-free for at least 6 months and the proportion of patients who have objective tumor response (complete or partial).

Key inclusion criteria: Carcinosarcoma of the ovary or uterus

Measureable disease

1-2 prior lines of treatment

No prior doxorubicin or liposomal doxorubicin

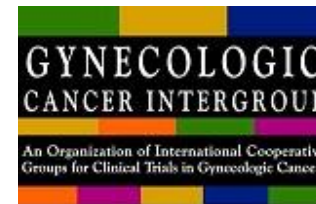
No prior olaratumab

Performance status 0-2

Adequate organ function



New Concept



GOG 3021

A Phase II Trial of Doxorubicin Combined with Olaratumab in the Treatment of Recurrent or Persistent Carcinosarcoma of the Uterus or Ovary

Enroll patients with measurable, advanced carcinosarcoma of the uterus or ovary, who have received 1-2 prior lines of systemic therapy for carcinosarcoma



Baseline CT CAP for RECIST measurements



Doxorubicin 60 mg/m² IV day 1, every 3 weeks for maximum 8 cycles

+

Olaratumab 15 mg/kg IV day 1 and day 8, every 3 weeks, maximum 8 cycles



CT CAP every 6 weeks (after every other cycle) to assess response by RECIST during cycles 1-8, then every 8 weeks until disease progression

Patients will remain on study treatment for a maximum of 8 cycles of doxorubicin + olaratumab provided CT imaging shows at least RECIST stable disease, and patient has not had unacceptable toxicity.