

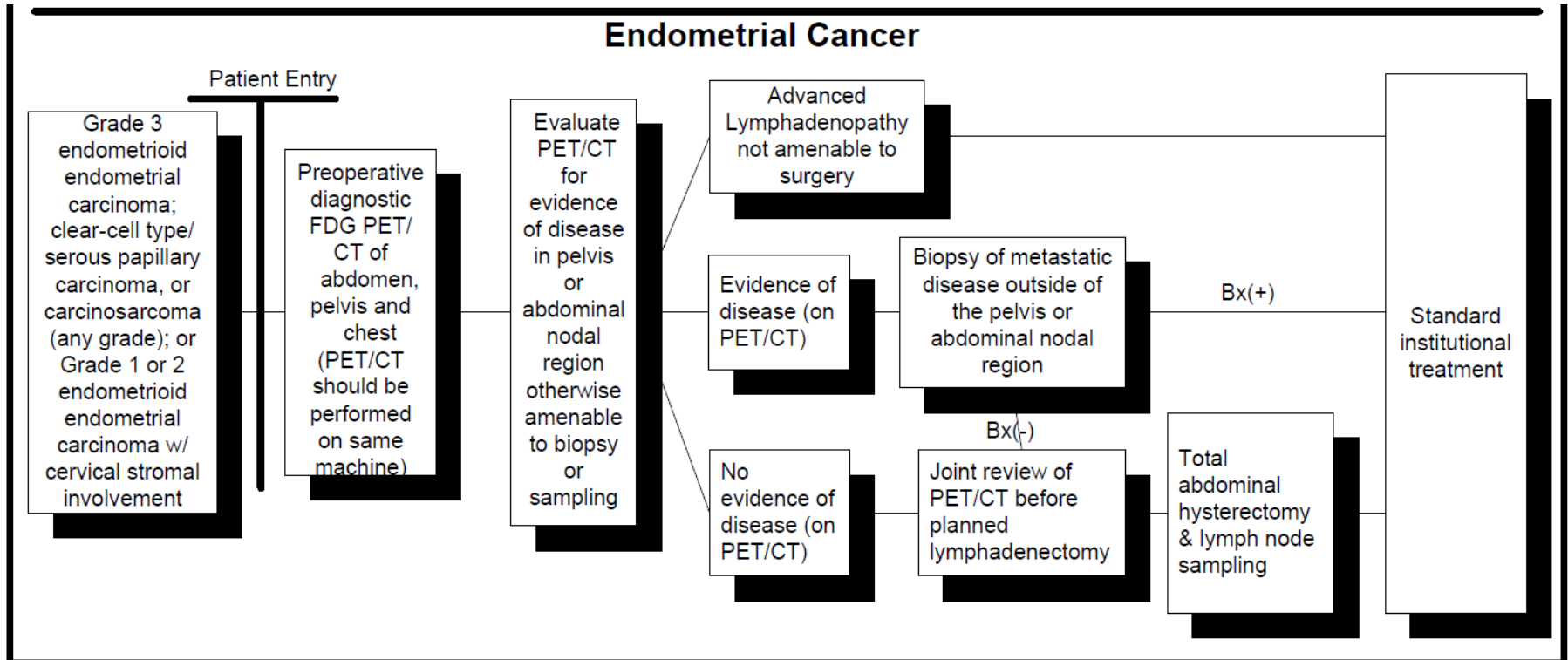


NIRG

ONCOLOGY

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Activated 9/24/07

Revised 6/9/08, 9/9/08, 11/12/08, 6/1/09, 11/16/09, 6/27/11, 7/2/12

Closed 12/3/12

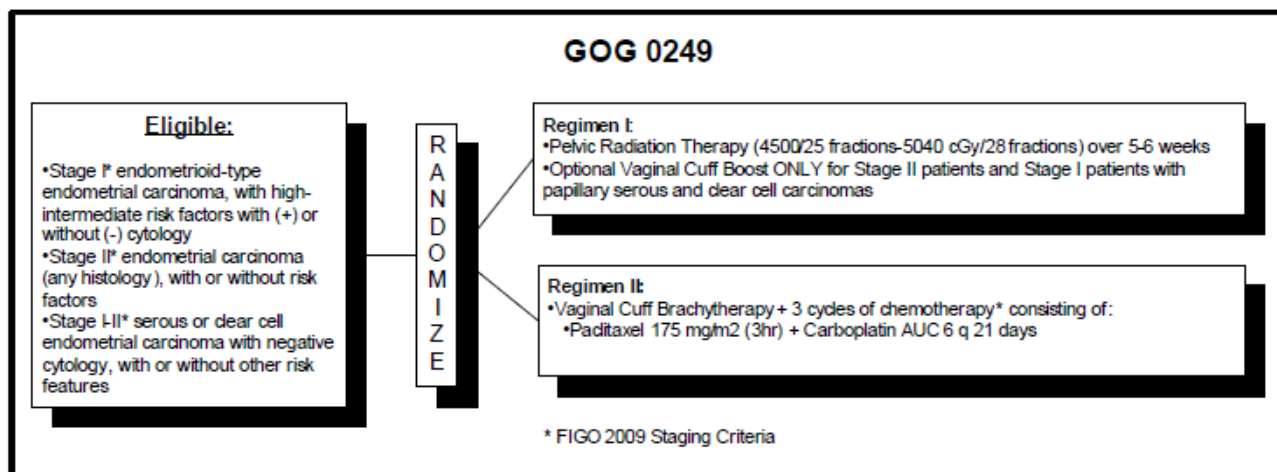
Final No. of patients: 384

Publications: Radiology 283:450 '17

GOG Protocol 249

Data Cut-off Date: 12/23/13

A Phase III Trial of Pelvic Radiation Therapy Versus Vaginal Cuff Brachytherapy Followed by Paclitaxel/Carboplatin Chemotherapy in Patients with High Risk, Early Stage Endometrial Carcinoma



Study Chairs: Scott McMeekin, MD, Marcus E Randall, MD, Carol Aghajanian, MD, Catheryn Yashar, MD, Vivian E von Gruenigen, MD, Michael Birrer, MD, PhD, and William Rodgers, MD

Protocol Statisticians: Ginny Filiaci, PhD and Helen Huang, MS (QOL)

Research Scientist: Heather Lankes, PhD, MPH

Data Coordinator: Randy Vogt, AS

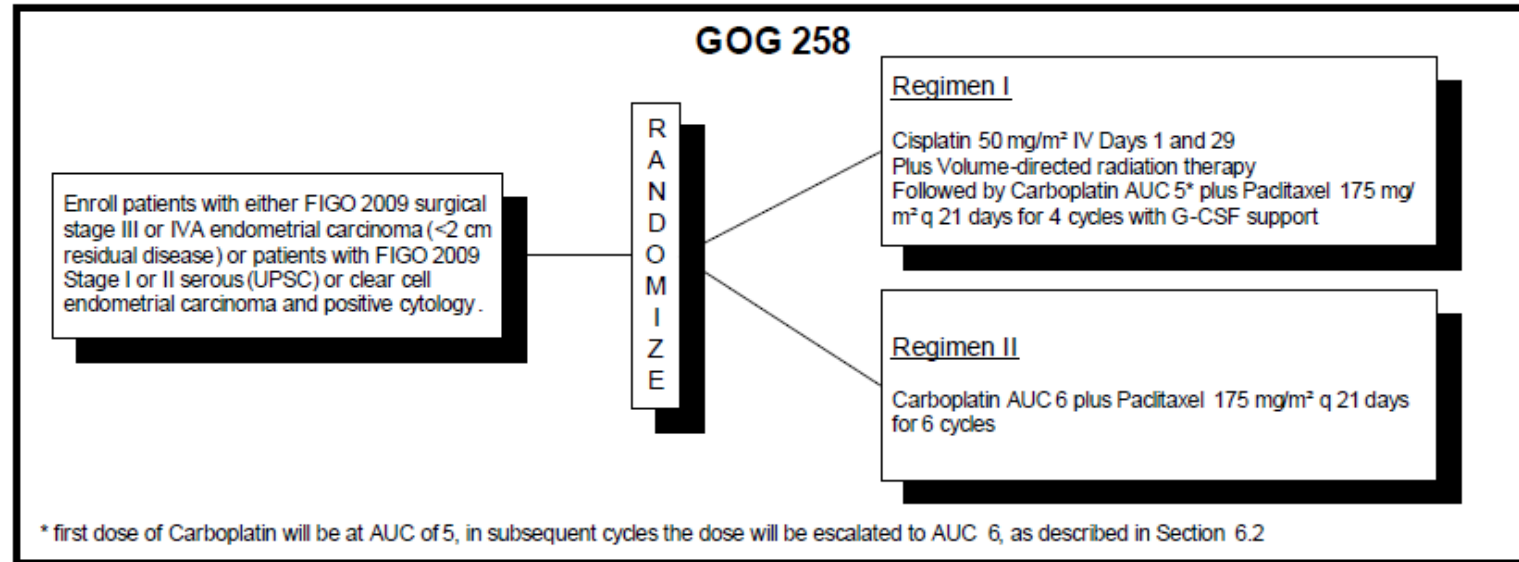
Activated: 3/23/09

Closed: 2/4/13

Final No. of patients: 562

Publications: SGO 2014, ASTRO 2017

A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel vs. Carboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial Carcinoma



Study Chairs: Daniela Matei, MD

Protocol Statisticians: Ginny Filiaci, PhD and Helen Huang (QOL)

Research Scientist: Heather Lankes, PhD, MPH

Data Coordinator: Randy Vogt, AS

Activated: 6/29/09

Closed: 7/28/14

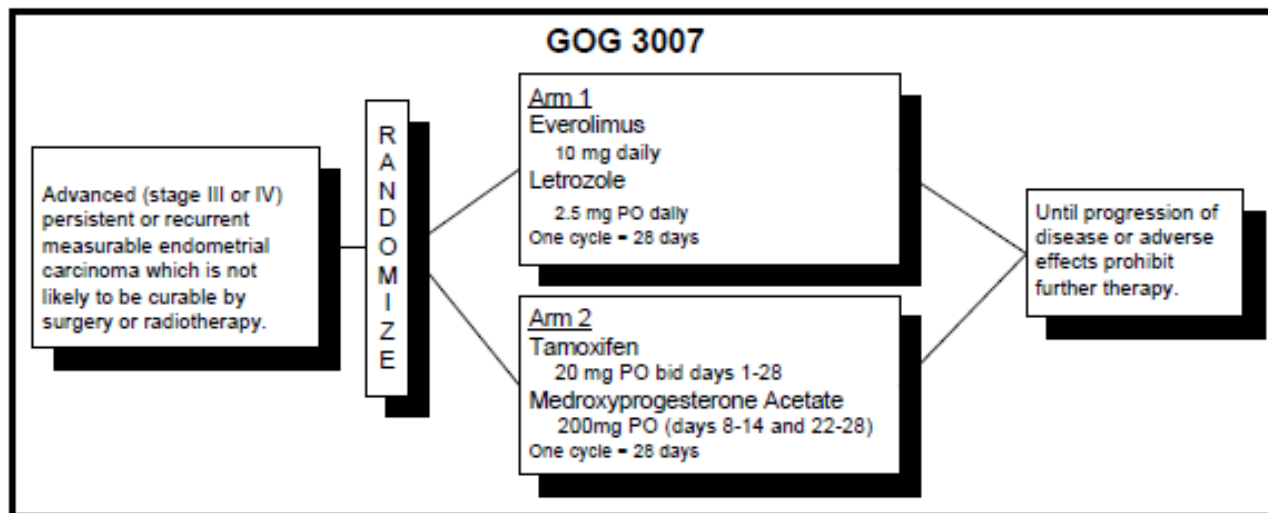
Final No. of patients: 813

Publications: ASCO 2017

GOG-3007

Report Based on Data Through 05/01/2017

A Randomized Phase II Trial of Everolimus and Letrozole or Hormonal Therapy (Tamoxifen/Medroxyprogesterone Acetate) in Women with Advanced, Persistent, or Recurrent Endometrial Carcinoma



Study Chairs: Brian Slomovitz, MD, Robert Coleman, MD

Protocol Statisticians: Virginia Filiaci, PhD

Research Scientist: Heather Lankes, PhD, MPH

Data Coordinator: Angela Kuras, BA, CCRP

Activated: February 19, 2015

Closed to accrual: April 18, 2016

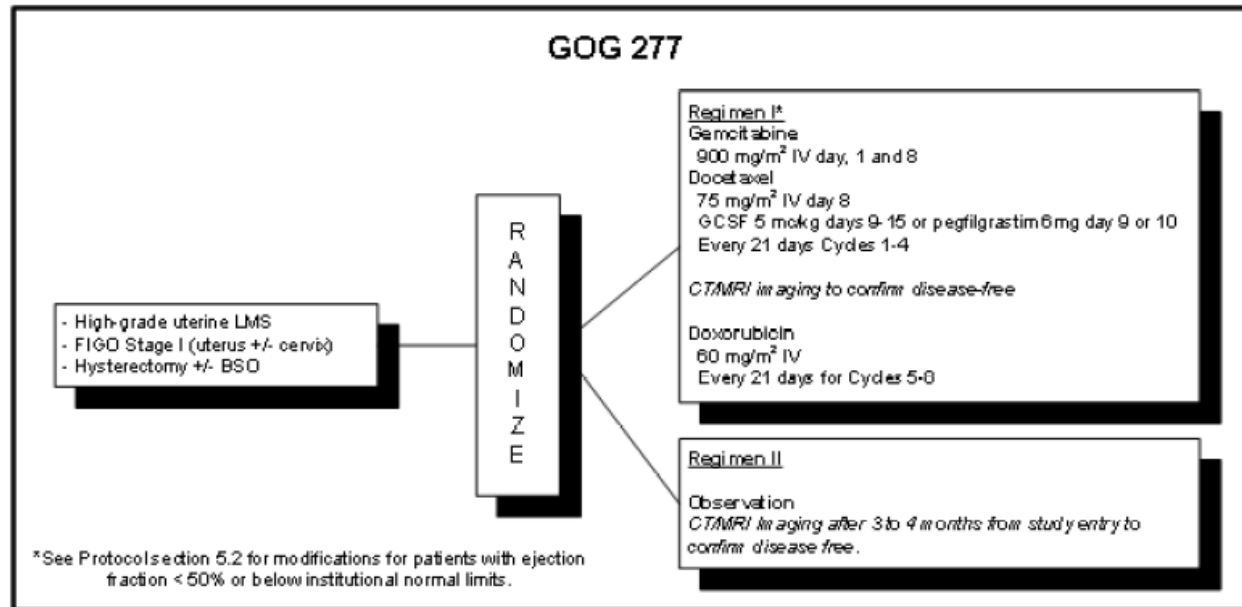
Final No. of patients: 74

Publications: Submitted SGO 2018

GOG-0277

Report Based on Data Through 10/31/2016

A Phase III Randomized Trial of Gemcitabine (NSC# 613327) Plus Docetaxel (NSC# 628503) Followed by Doxorubicin (NSC# 123127) Versus Observation for Uterus-Limited, High-Grade Uterine Leiomyosarcoma



Study Chairs: GOG: Martee Hensley, MD; NCRN: Helen Hatcher, MD; EORTC: Isabelle Ray-Coquard, MD, PhD, James Hoffman, MD, Helen Michael, MD

Protocol Statisticians: Virginia Filiaci, PhD

Data Coordinator: Bette Stonebraker, CCRA

Activated: 6/4/2012

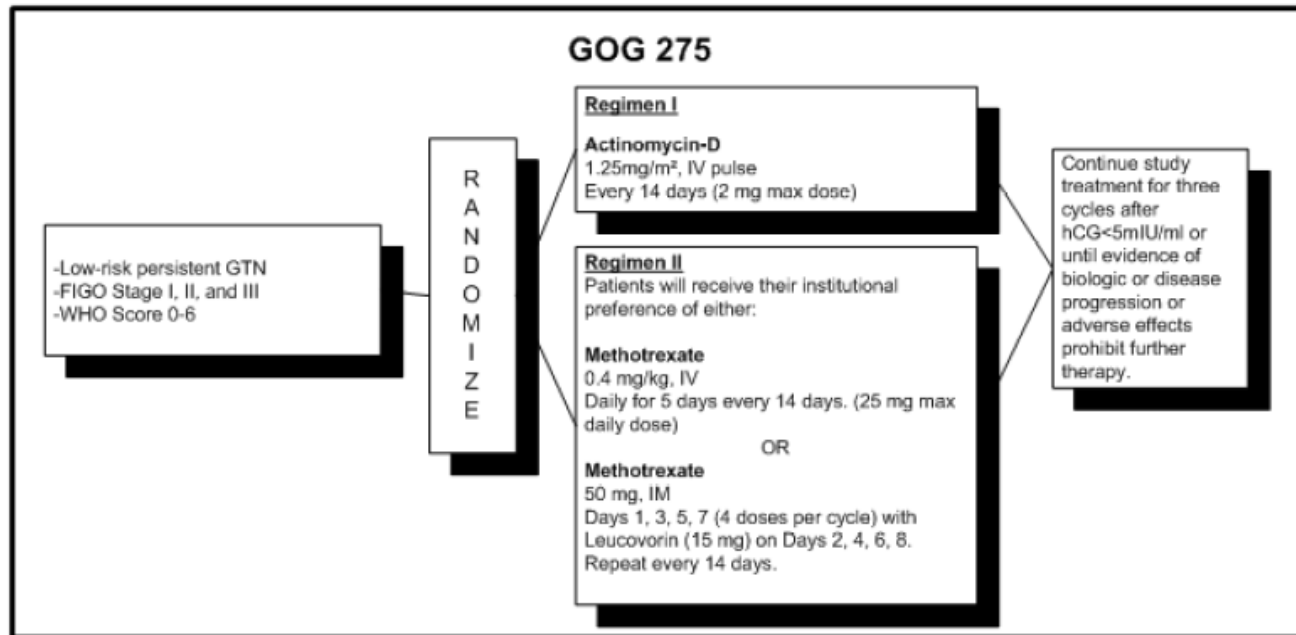
Closed to Accrual: 9/20/2016

Final No. of patients: 38/216

Publications: Doubtful

International Rare Cancers Initiative - Gynaecological sarcoma

A Phase III Randomized Trial of Pulse Actinomycin-D versus Multi-Day Methotrexate for the Treatment of Low-Risk Gestational Trophoblastic Neoplasia NCT #01535053



Study Chairs: Julian Schink, MD, Raymond Osborne, MD, John Tidy, MD, Helen Michael, MD, Michael Seckl, MBBS, BSc, PhD, FRCP, Jeanne Carter, PhD

Protocol Statisticians: Virginia Filiaci, PhD and Helen Huang, MS

Data Coordinator: Bette Stonebraker, CCRP

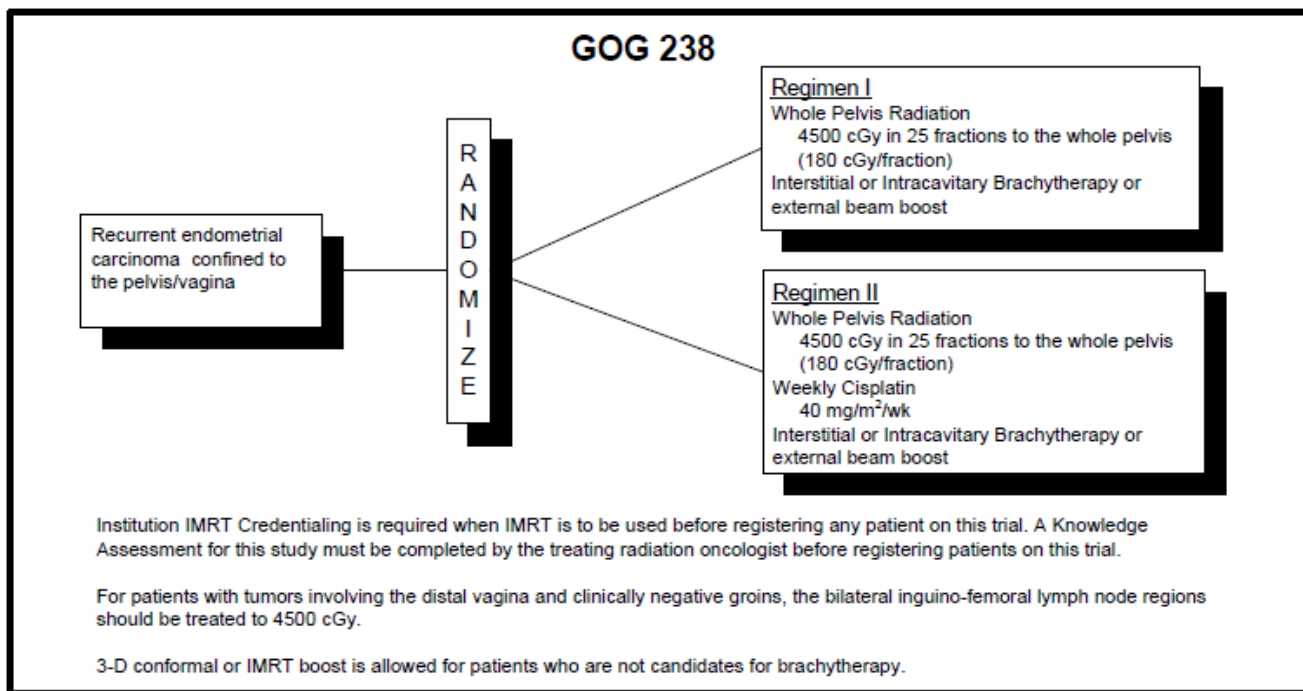
Activated: 06/18/2012

Final No. of patients: 57/384

Closed to accrual: 09/20/2016

Publications: ISSTD 2017

A Randomized Trial of Pelvic Irradiation With or Without Concurrent Weekly Cisplatin in Patients With Pelvic-only Recurrence of Carcinoma of the Uterine Corpus



Study Chair: Jonathan M. Feddock, M.D., Julian Schink, MD, Penny Anderson, MD, Richard Zaino, MD

Protocol Statisticians: Virginia Filiaci, PhD

Data Coordinator: Izabela Frak

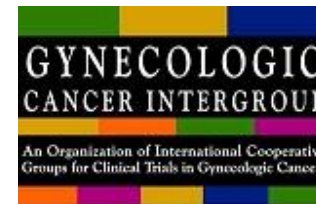
Activated: 2/25/2008

Planned No. of patients: 154

Current accrual: 124



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.