Protocol Title: Phase II Trial Evaluating Cisplatin (NSC# 119875) and Gemcitabine (NSC# 613327) Concurrent with Intensity-Modulated Radiation Therapy (IMRT) in the Treatment of Locally Advanced Squamous Cell Carcinoma of the Vulva (NCT #01595061)

Target Population: Adult and senior females, ages 18 and older with Stage IIIA – IVA Vulvar Cancer.

Summary: This phase II trial studies hopes to show how well radiation therapy works when given with gemcitabine hydrochloride and cisplatin work in treating patients with squamous cell cancer of the vulva that has spread from where it started to nearby tissue or lymph nodes. Specialized radiation therapy, along with gemcitabine hydrochloride and cisplatin, will be done to test if this method will kill more tumor cells.

Key Inclusion Criteria:
- Patients with locally advanced previously untreated squamous cell carcinoma of the vulva.
- Patients with T2 or T3 primary tumors (N0-3, M0) not amenable to surgical resection by standard radical vulvectomy.
- Absolute neutrophil count ≥ 1500/mcl.
- Bilirubin ≤ 1.5 x upper limit of normal (ULN).
- Creatinine ≤ 1.5x institutional (ULN) OR calculated creatinine clearance ≥ 60 mL/min.
- AST and ALT ≤ 3.0 x ULN.
- Alkaline phosphatase ≤ 3 x ULN.
- Patients judged capable of tolerating a radical course of chemoradiation therapy.
- Patients must not be eligible for a higher priority Gynecologic Oncology Group (GOG) protocol.
  - If one exists; in general, this would refer to any active GOG Phase III protocol or Rare Tumor protocol for the same patient population.
- Patients must have signed an approved informed consent and authorization permitting release of health information.
- Patients with a GOG performance status of 0, 1, or 2.

Key Exclusion Criteria:
- Patients with recurrent carcinoma of the vulva regardless of previous treatment.
- Patients who have received prior pelvic radiation or cytotoxic chemotherapy.
- Patients with vulvar melanomas or sarcomas.
- Patients with circumstances that will not permit completion of the study or the required follow-up.
- Patients with evidence of active septicemia, severe infection, gastrointestinal bleeding or severe gastrointestinal symptoms requiring medical or surgical therapy.
- Patients with a history of other invasive malignancies, with the exception of non-melanoma skin cancer, are excluded if there are any evidence of other malignancy being present within the last five years; patients are also excluded if their previous cancer treatment contraindicates this protocol therapy.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT01595061