Protocol Title: A Randomized Phase II Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer.

Target Population:
- Stage IB2 – IVA Cervical Cancer
- Cervical Adenocarcinoma or Adenosquamous Carcinoma
- Cervical Squamous Cell Carcinoma, not otherwise specified
- Stage II – IVB Vaginal Cancer
- Vaginal Adenocarcinoma or Adenosquamous Carcinoma
- Vaginal Squamous Cell Carcinoma, not otherwise specified

Summary: This randomized phase II trial studies radiation therapy and Cisplatin with Triapine (3AP) to see how well they work compared to the standard radiation therapy and Cisplatin alone in treating patients with newly diagnosed Stage IB2, II, or IIIB-IVCervical Cancer or Stage II-IVAVaginal Cancer.

Key Inclusion Criteria:
- Patient has a new, unrated histologic diagnosis of Stage IB2, II, IIIB, or IVA Squamous, Adenocarcinoma, or Adenosquamous Carcinoma of the Uterine Cervix or Stage II-IVA Squamous, Adenocarcinoma, or Adenosquamous Carcinoma of the Vagina not amenable to curative surgical resection alone.
  - Presence or absence of para-aortic lymph node metastasis based on pre-therapy 18F-FDG PET/CT. If baseline 18F-FDG PET/CT identifies hypermetabolic para-aortic disease, patients won’t be eligible.
  - Patient must be able to tolerate imaging requirements of an 18F-FDG PET/CT scan.
- Gynecologic Oncology Group performance status of 0, 1, or 2.
- Patient has a life expectancy of greater than 20 Weeks.
- Patient does not have uncontrolled diabetes mellitus.
- Patient does not have known brain metastases.
- Patient does not have HIV. HIV-positive patients receiving combination antiretroviral therapy are ineligible.
- Patient does not have a known allergy to compounds of similar or biologic composition as Triapine.
- Patient is not actively breastfeeding.

Key Exclusion Criteria:
- Patient has another concurrent active invasive malignancy.
- Patient has had a prior invasive malignancy diagnosed within the last 3 Years, except non-melanoma skin cancer or prior in situ carcinoma of the cervix.
  - Patients are excluded if they have received prior pelvic radiotherapy for any reason that would exceed radiation dose tolerance of normal tissue.
- Patient has uncontrolled intercurrent illness including, but not limited to, symptomatic congestive heart failure, unstable angina pectoris, myocardial infarction within six months of protocol initiation, cardiac arrhythmia within 6 Months of protocol initiation.
- Patient is receiving another investigational agent for the treatment of cancer.
- Patient is currently pregnant; patient must agree to use two forms of birth control.
- Patients who have had a hysterectomy or are planning to have an adjuvant hysterectomy following radiation as part of their cervical cancer treatment are ineligible.
- Patients scheduled for adjuvant consolidation chemotherapy at conclusion of standard chemoradiation.
- Patients with self-reported or known diagnosis of Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency as the condition interferes with Triapine antidote metabolism.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT02466971