Study | Para-aortic LN irradiation using Proton Beam Radiotherapy for Isolated Para-aortic recurrence of Gynecologic cancer
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Additional Info | National Cancer Center Korea
Institution | Study Purpose
Recruitment Status | 1. Study Start Date:
| 2. Estimated Primary Completion Date:
| 3. Estimated Study Completion Date:
| 4. Estimated Enrollment:
Primary Aims | 1. To evaluate the effect of proton beam radiotherapy to the para-aortic LN (PAN) chain as a first treatment modality or re-treatment modality after previous irradiation at the same site (2 yr progression-free survival).
Secondary Aims | 1. To evaluate whether proton beam radiotherapy reduced radiation-associated morbidity and the patients’ quality of life.
Methods | 1) proton beam : 45GyE to the microscopical disease - reduction of field - 60Gy or more depending on the size of the gross node enlargement (proton RBE 1.1) fraction size 2.5 Gyx18F --> cone-down Boost depending on the tumor size.
The dose can be reduced to 40GyE/16F if systemic chemotherapy of a kind which can increase the radiation effect around 10%.
Area of microscopic disease 45GyE/18F/3.5wks(EQD2 46.8 Gy)
50Gy for node with short diameter ≤1cm (EQD2 52 Gy)
55 Gy for node 1< ≤1.5cm (EQD2 57.2 Gy)
60 Gy for node 1.5< ≤2.0cm (EQD2 62.4 Gy)
65 Gy for node 2.0< ≤2.5 cm (EQD2 67.6 Gy)
70 Gy for node 2.5< ≤3cm (EQD2 72.8 Gy)
* Biologically equivalent dose in 2 Gy fractions (EQD2)
2) Combined chemotherapy : cisplatin weekly, 5-FU/cisplatin, Taxol-based regimen, or other agents which are being used for the other gynecologic protocol
### Eligibility

1) Patients with Histologically confirmed gynecologic cancer who have para-aortic LN as the only systemic recurrence out of pelvis
   a) Postoperative- or Postradiotherapy-recurrence at the para-aortic LN area
   b) Prior radiotherapy± chemotherapy to the same area of interest is allowed when the recurrent lesion is resistant to other modality or there is a residual lesion after salvage chemotherapy.

2) Disease-specific criteria
   ① Uterine cervical cancer : isolated recurrence at the para-aortic LN chain
   ② Uterine cancer (endometrial cancer, uterine sarcoma, undifferentiated cancer of the uterine body): Isolated recurrence at the para-aortic LN chain or symptom-causing metastatic para-aortic recurrence regardless whether chemotherapy has been given or not.
   ③ Ovarian cancer : Isolated recurrence at the para-aortic LN chain or symptom-causing metastatic para-aortic recurrence regardless whether chemotherapy has been given or not.
   ④ Other gynecologic cancer with isolated para-aortic, or symptom-producing para-aortic metastases even if the lesion to be treated by proton beam is not single lesion

* The status of an isolated recurrence is determined from the general metastatic work-up such as positron emission tomography, abdomino-pelvic CT and/or MRI, or laparoscopic or other surgical exploratory procedures if necessary as one of the staging procedure or as an attempt to remove the lesion

3) Age 18-80 years
4) Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) 0-2

### Exclusion Criteria