

| | |
|------------------------|---|
| Study | Para-aortic LN irradiation using Proton Beam Radiotherapy for Isolated Para-aortic recurrence of Gynecologic cancer |
| Principle Investigator | Joo Young Kim, M.D. |
| Contact | Joo Young Kim, M.D. jooyoungcasa@ncc.re.kr ; +82-31-920-1724 |
| Additional Info | |
| Institution | National Cancer Center Korea |
| Recruitment Status | 1. Study Start Date: 2. Estimated Primary Completion Date: 3. Estimated Study Completion Date: 4. Estimated Enrollment: |
| Study Purpose | |
| 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 ≤ 1 cm (EQD2 52 Gy) 55 Gy for node $1 < \leq 1.5$ cm (EQD2 57.2 Gy) 60 Gy for node $1.5 < \leq 2.0$ cm (EQD2 62.4 Gy) 65 Gy for node $2.0 < \leq 2.5$ cm (EQD2 67.6 Gy) 70 Gy for node $2.5 < \leq 3$ cm (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 |

| Study | Para-aortic LN irradiation using Proton Beam Radiotherapy for Isolated Para-aortic recurrence of Gynecologic cancer |
|--------------------|--|
| Eligibility | <p>1) Patients with Histologically confirmed gynecologic cancer who have para-aortic LN as the only systemic recurrence out of pelvis</p> <ul style="list-style-type: none"> 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. <p>2) Disease-specific criteria</p> <ul style="list-style-type: none"> 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 <p>* 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</p> <p>3) Age 18-80 years</p> <p>4) Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) 0-2</p> |
| Exclusion Criteria | |