GOG 278

PROTOCOL GOG-0278
EVALUATION OF PHYSICAL FUNCTION AND QUALITY OF LIFE (QOL) BEFORE AND AFTER NON-RADICAL SURGICAL THERAPY (EXTRA FASCIAL HYSTERECTOMY OR CONE BIOPSY WITH PELVIC LYMPHADENECTOMY) FOR STAGE IA1 (LVSI+) and IA2-IB1 (≤2CM) CERVICAL CANCER

NCI Version Date 09/20/2012

POINTS:
PER CAPITA - 20
MEMBERSHIP - 6

• Estimated enrollment: 600 pts

NCT01649089
Minimum sample size = 200
May enroll up to 600 subjects over 3 stages

GOG 278

Studying the Physical Function and Quality of Life Before and After Surgery in Patients With Stage I Cervical Cancer

Women with IA1-IB1 (<2cm) carcinoma of the cervix who have been consented for surgery will be approached for study participation and entered on study.

Conization with pelvic lymphadenectomy (fertility preservation)

Simple hysterectomy with pelvic lymphadenectomy (no wish for future fertility) group

Medical Information/Physician Checklist:
- Pregnancy, fertility and intention to conceive (Pre-op)
- Pre-operative Study Survey (15 minutes to complete): Bladder and Bowel Function Items
- Female Functioning Index & 2 PROMIS items
- GCLQ-Gyn Cancer Lymphedema Questionnaire
- Functional Assessment Cancer Therapy FACT-Cx
- Impact of Events Scale (IES)
- Conization Group only Reproductive Items (ICF & RCS)

Medical Information/Physician Checklist:
- Pregnancy, fertility and intention to conceive (Pre-op)
- Pre-operative Study Survey (15 minutes to complete): Bladder and Bowel Function Items
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- Impact of Events Scale (IES)

Post-Operative
(Patients requiring adjuvant therapy will be removed from the study)

Conization with pelvic lymphadenectomy (fertility preservation) group

Simple hysterectomy with pelvic lymphadenectomy (no wish for future fertility) group

Assessments Schedule Post-Operatively
- 4-6 weeks Post-Op and every 6 months (6, 12, 18, 24, 30, 36) for three years

Medical Information/Physician Checklist:
- Pregnancy, fertility and intention to conceive (Post-Op)
- Post-Operative Study Survey (15 minutes to complete): Bladder and Bowel Function Items
- Female Functioning Index & 2 PROMIS items
- GCLQ-Gyn Cancer Lymphedema Questionnaire
- Functional Assessment Cancer Therapy FACT-Cx
- Impact of Events Scale (IES)
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Medical Information/Physician Checklist:
- Pregnancy, fertility and intention to conceive (Post-Op)
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- Female Functioning Index & 2 PROMIS items
- GCLQ-Gyn Cancer Lymphedema Questionnaire
- Functional Assessment Cancer Therapy FACT-Cx
- Impact of Events Scale (IES)
PROTOCOL GOG-0279
A 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

NCI Version Date: 11/02/2012
Includes Revision #1

POINTS:
PER CAPITA - 20
MEMBERSHIP – 3

Study Chair: NS Horowitz

Target 52 evaluable patients

NCT01595061
AIM2CERV/GOG 3009

- High Risk, Locally Advanced Cervical Cancer
- FIGO Stage I-II with positive pelvic nodes
- FIGO Stage III-IVA
- Any Figo Stage with para-aortic nodes

Randomization 1:2 Reference and Treatment Groups

Primary Objective is Progression Free Survival

NCT02853604
Newly diagnosed uterine cervix cancer
• Squamous
• Adenosquamous
• Adenocarcinoma

Clinical stage bulky (> 5 cm) IB2, or
Clinical stage II, IIIB, or IVA followed by
Negative para-aortic nodal staging by PET/CT

Stratify para-aortic node-negative patients by:
  a. Age (≤ 45 years or > 45 years)
  b. Performance status (0, 1, or 2)
  c. Intensity Modulated Radiation Therapy (yes or no)
  d. Stage (≤ clinical stage II, or ≥ clinical stage III)

RANDOMIZE

Arm 1:
• Radiation
• Cisplatin

Arm 2:
• Radiation
• Cisplatin
• Triapine

PI = TREY LEATH MD
N = 188
Enrollment to June 2017 = 50
Primary Endpoint = RFS

NCT02466971

NTO-1151-Triapine:
• Small molecule chelator –
  Inhibits ribonuclease
  reductase / ribonucleotide
  reductase inhibitor

Radiation: 45 Gy / 25 fractions of 1.8 Gy + 5.4 Gy / 3 fraction parametrium boost + 40 Gy LDR or 30 Gy HDR brachytherapy

Cisplatin: X1 weekly cisplatin 40 mg/m² (maximum 70 mg) days 2, 9, 16, 23, 30 of radiation (5 total infusions; a sixth administration on day 36 is permissible at the treating physician’s discretion.)

Triapine: X3 weekly 3-aminopyridine-2-carboxaldehyde thiosemicarbazone (Triapine) 25 mg/m² (maximum 50 mg) days 1, 3, 5, 8, 10, 12, 15, 17, 19, 22, 24, 26, 29, 31, 33 of radiation (15 total infusions)
- Recurrent, persistent, and/or metastatic cervical cancer
- Progressed within 6 months of the last dose of platinum

REGN2810 350 mg Q3W, for up to 96 weeks

Physicians choice chemotherapy

Pemetrexed 500 mg/m² Q3W
Topotecan 1 mg/m² daily for 5 days, Q21 days
Irinotecan 100 mg/m² days 1, 8, 15, & 22, followed by 2 weeks rest (6-week cycle)
Vinorelbine 30 mg/m² days 1 & 8, Q21 days
Gemcitabine 1000 mg/m² on days 1 & 8, Q21 days

REGN2810, a fully human monoclonal antibody against programmed death-1 (PD-1)

NCT03257267