The OUTBACK Trial

6.1 Study Schema

Patients with stage IB1 & positive nodes, IB2, II, III, IIIb or IVA cervical cancer who have given informed consent

 Eligible patients

 RANDOMISE

 Max 6 weeks

 Arm A – Control Arm
 Concurrent chemoradiation

 Arm B – Intervention Arm
 Concurrent chemoradiation followed by adjuvant chemotherapy

 Follow up for a minimum of 3 years
RTOG 1174/ LU205972 OUTBACK TRIAL: A Phase III Trial Of Adjuvant Chemotherapy As Primary Treatment For Locally Advanced Cervical Cancer Compared To Chemoradiation Alone: The Outback Trial.

Eligibility:

Locally advanced cervical cancer suitable for primary treatment with chemoradiation with curative intent, in addition to:

1. FIGO 2008 stage IB1 & node positive, IB2, II, IIIB or IVA disease.

2. Age 18 years or older

3. ECOG performance status 0 – 2

4. Histological diagnosis of squamous cell carcinoma, adenocarcinoma or adenosquamous cell carcinoma of the cervix

5. WBC ≥ 3.0 x 10^9/L and ANC ≥ 1.5 x 10^9/L

6. Platelets ≥ 100 x 10^9/L

7. Bilirubin ≤ 1.5 x ULN

8. AST or ALT ≤ 2.5 x ULN

9. Adequate renal function: creatinine ≤ ULN (CTC Grade 0) or calculated creatinine clearance (Cockcroft-Gault Formula) ≥ 60ml/min or ≥ 50 ml/min by EDTA creatinine clearance
RTOG 1174/ OUTBACK TRIAL /LU205972:
A Phase III Trial Of Adjuvant Chemotherapy As Primary Treatment For Locally Advanced Cervical Cancer Compared To Chemoradiation Alone: The Outback Trial

Exclusion Criteria:

1. Any previous pelvic radiotherapy

2. Para-aortic nodal involvement above the level of the common iliac nodes or L3/L4 (if biopsy proven, PET positive or ≥ 15mm short axis diameter on CT)

3. FIGO 2008 stage IIIA disease

4. Patients assessed at presentation as requiring interstitial brachytherapy treatment

5. Patients with bilateral hydronephrosis unless at least one side has been stented and renal function fulfils the required inclusion criteria

6. Previous chemotherapy for this tumour

7. Evidence of distant metastases.

8. Prior diagnosis of Crohn’s disease or ulcerative colitis

9. Peripheral neuropathy > grade 2 (as per CTCAE v4)

10. Patients who have undergone a previous hysterectomy or will have a hysterectomy as part of their initial cervix cancer therapy

11. Patients with other invasive malignancies, with the exception of non-melanoma skin cancer and in situ melanoma, who had (or have) any evidence of the other cancer present within the last 5 years

12. Patients who are pregnant or lactating