A Phase III trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone: THE OUTBACK TRIAL (ANZGOG 0902, GOG 0274, RTOG 1174)

Current Status

<table>
<thead>
<tr>
<th>Group</th>
<th>Active sites</th>
<th>Pts randomised</th>
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<td>57</td>
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</table>

Trial Newsletter—May 2013

Message from the Study Chair

Thankyou for your ongoing commitment to completing recruitment to OUTBACK.

I would like to highlight a couple of points of clarification:

1. Under the amended protocol (Version 4.0) we have specified that if sites are able to access both a MRI pelvis and PET/CT at baseline then a separate CT Chest/Abdo/Pelvis is not required. Hopefully this change will reduce the number of scans needed for many women.

2. Section 6.2 entitled “Randomisation” clarifies the definition of node positive disease which should be used for the purposes of stratifying the patient as having pelvic or common iliac nodal involvement.

Specifically patients should be considered node positive if ANY of the following is present:

- A) Pelvic or common iliac node positive on surgical nodal biopsy or resection that leads to abandonment of a planned hysterectomy
- B) Pelvic or common iliac node positive on staging PET/CT scan
- C) Pelvic or common iliac node positive on staging CT or MRI scan as per RECIST 1.1 criteria ie ≥ 15mm in short axis diameter

Study coordinators and research nurses should liaise with investigators to carefully interpret the diagnostic imaging reports. Of note sometimes the names of individual nodes within the pelvis are used eg internal iliac rather than ‘pelvic’ nodes.

This section has been written this way, on the basis of statistical advice that we need to be consistent across all sites, including those not able to access PET scans for the purposes of stratification in the study.

In the event of conflicting imaging findings, radiation oncologists should make a clinical decision after reviewing all available information about how best to plan the radiotherapy for a patient.
Baseline MRI data
The following data are requested from those sites who have pre-treatment MRI data available.

Corpus invasion (yes / no)
It is important that the reporting radiologist looks for corpus invasion and specifically reports as corpus invasion ‘present’ or ‘not present’. If corpus invasion has not been specifically commented on in the report, it may be incorrectly interpreted by the person completing the CRF as “corpus not involved”.

Tumour volume
Please request your reporting radiologist to calculate tumour volume using following formula.
- Product of three diameters × pi/6
Or
- MRIVol: [Tranverse diameter Tumour]×[Longitudinal diameter Tumour]×[AP diameter Tumour]×0.5236

The transverse diameter is best measured in axial cuts and the longitudinal (or cranio-caudal diameter along the long axis of the uterus and not along the patient’s cranio-caudal axis) and AP diameters are best measured in the sagittal view.

Please see the enclosed MRI reporting protocol for more information.

QOL - Time points
Collecting QOL information is an important part on the OUTBACK trial. Please ensure that a QOL booklet is presented to patients at all the given time points.
- Baseline
- Adjuvant chemotherapy cycles 1 - 4 (for patients in Arm B)
- End of Treatment
- Follow-up: 6, 9, 12, 15, 18, 21, 24, 30, 36 months from randomisation

We have noticed that follow-up completion rates are lower than expected, mainly because QOL booklets are not presented to patients by mistake.
We would like to ask everyone to pay particular attention to the patients' follow-up schedule and organise for QOL booklets to be ready when the patients come for their visit.
That way we will be able to collect valuable information about how they feel once they have finished their treatment.
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InForm database - Setting up the password recovery function

1. Log in to InForm as normal.
2. Click your name at the top left of the screen. You will see the Password Settings screen.
3. Leave the ‘Change Password’ section blank (items 2-4) (your password will not be changed).

In the Password Recovery Information section:
4. Email Address: enter your own personal email address – this will be used to send you a temporary password if you forget your password later
5. Question: enter a question that only you will know the answer to, e.g. Mother’s maiden name
6. Response: enter the answer to the question. Please be very careful: if you ever forget your password, you will need to enter this response exactly as it is typed, including capitals/lower case/punctuation etc.
7. Click Submit
8. Click Logout

Frequently Asked Questions (FAQ)

Q: My patient has progressed. Do I need to continue follow-up?
A: Yes. Once a patient progresses, she is in survival follow-up. That means that follow-up information about survival still needs to be collected. QOL and toxicity assessments are no longer required once a patient has relapsed.

Q: My patient had an MRI for baseline RECIST and a CT for follow-up RECIST. Is that a problem?
A: Yes. It is not possible to compare an MRI to a CT. The same type of scan needs to be done for baseline and follow-up RECIST measurements.

Q: Where do I record the baseline toxicity assessment in InForm?
A: In InForm, NO baseline toxicity assessment needs to be recorded. The first toxicity visit in InForm is the one done after cycle 1 of cisplatin, just before cycle 2 of cisplatin.