

ICORG 06-35: PROSPECTIVE EVALUATION OF PET-CT SCAN IN PATIENTS WITH NON-OPERABLE OR NON-RESECTABLE NSCLC TREATED BY RADICAL 3-DIMENSIONAL CONFORMAL RADIATION THERAPY

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**Purpose:** Positron Emission Tomography (PET) scans have demonstrated a significant increase in accuracy in the assessment of tumour extension in Non-Small Cell Lung Cancer (NSCLC), by establishing a more accurate diagnosis of local, regional nodal and metastatic tumour extension. Presently a PET scan is considered gold standard in pre-treatment assessment in patients (pts) with apparently localised NSCLC prior to considering any radical local approach, e.g. surgery or radical radiotherapy. This improved accuracy in tumour extension assessment has led to PET scan integration in the design of radiotherapy. Planning studies (Maastricht1) have demonstrated:- a significant difference between CT scan vs PET scan based volume and plan; a significant reduction of inter/intra-observer variation by using PET scan based tumour delineation techniques.

**Materials:** ICORG 06-35, 'A prospective evaluation of PET-CT Scan in patients with non-operable or non-resectable NSCLC treated by Radical 3-Dimensional Conformal Radiation Therapy', opened in August 2007 in St. Luke's Hospital. The trial is co-ordinated by a Radiation Therapist (RT) and will employ a two-fold approach: - 1: Pilot study (n=10) to evaluate the technical feasibility of integrating PET-CT to planning-CT fusion into clinical practice in our institution. 2: A Phase II clinical trial (n=40, including 10 from the pilot study), to evaluate the safety of PET-CT scan based radiotherapy in terms of loco-regional control, through a precise evaluation of the intra-thoracic pattern of recurrence. 1) Conventional CT-scan Based Radiotherapy Technique

All eligible pts in this trial will undergo 3D-CRT planning and treatment while lying supine, breathing freely. The pt is set-up in the treatment position using a lung immobilisation device (lungboard). The pt then undergoes a noncontrast CT Scan (General Electric Lightspeed 4 slice CT) whilst breathing freely. The CT scan is acquired using the standard lung protocol, with a 3.27 mm helical thickness and 1.5:1 pitch. An A/P and lateral topogram is taken to determine scanning margins. A single axial slice is taken to check for pt rotation prior to acquiring the complete number of axial slices. The axial slices are taken in 3.27 mm intervals and the tabletop height is recorded. 2) PET-CT scan Acquisition Pts then undergo a PET-CT scan in Blackrock Clinic, Dublin (our institution does not currently have PET-CT facilities) using a flat tabletop, the appropriate lung immobilisation device, and laser alignment to ensure that the patient is in the same treatment position with the same isocentre as the planning CT scan. A report of the PET-CT with specific reference to the primary tumour volume is issued by Blackrock Clinic. Two RTs from St. Luke's Hospital attend the Blackrock Clinic for the PET-CT scan to ensure that the correct immobilisation and set-up procedures are used. A 'cold session' (pre-injection phase) is used to familiarise the pt with the procedure. This enables the RTs to have minimal ptcontact post- injection. Once injected ('hot session'), the pt is radioactive and the RTs must adopt the ALARA principle.

Exposure to the RTs is recorded. Two separate plans, using the planning

CT-GTV and the PET-CT-GTV are outputted. The pt will be treated using the PET-CT-GTV. All pts in the trial undergo standard post-treatment follow-up, including repeated 3 monthly CT scan of the thorax. The primary end-point of the pilot study will be the extent of successful delivery of PET-CT scan based radiotherapy - a rate of above 60% will be considered acceptable.

**Results:** To mid-March, 10 pts have been recruited to the pilot study out of 82 screened - 4 of these pts have subsequently been withdrawn as follows:  
- An unanticipated delay in receiving the PET scan report coupled with initial fusion software problems led to the first pt being withdrawn in order to avoid unnecessarily delaying the pt's treatment start date. The second pt was unable to tolerate the lungboard. This subsequently led to an ability to tolerate this device being included as part of the eligibility criteria. One pt died prior to commencing treatment from a non-cancer related illness. One pt was shown to have rapid disease progression with associated deterioration, and received palliative RT. The process of fusing scans for the pilot study has proven quite challenging to date. This is due to: - Set-up errors, pts free-breathing, the time lapse between scans, the different duration of the scans (CT vs. PET), image quality, Lat Sup/Inf and Rotational movement. In addition, the importance of carefully selecting registration points and an appropriate threshold value (associated impact on volume) cannot be underestimated.

**Conclusions:** Results from the pilot study will show the technical feasibility of integrating PET-CT to planning-CT fusion into clinical practice in our institution, and will determine whether or not we can safely advance to the next phase of this trial.  
1De Ruyscher D et al. Int J Rad Onc Bio Phys 2005;62:988-994