Protocol PET BOOST

Dose Escalation by Boosting Radiation Dose Within the Primary Tumor Using FDG-PET-CT Scan in Stage IB, II and III NSCLC.

This is the trial summary as assessed on clinicaltrials.gov on 01/12/2014.

Minor changes in the protocol may occur. You can check this on this direct link:

http://clinicaltrials.gov/ct2/show/NCT01024829?term=PET+Boost&rank=1

Trial design :

Increasing ("boosting") the radiation dose for patients with non-small cell lung carcinoma to the individual maximal dose which can safely be given. The question is if patients should receive this boost on the whole tumor on part of the tumor. Therefore patients are randomized for one of these two treatment options. All patients will receive 24 radiations. Dose increasement will be enabled by a so called integrated boost.

Inclusion criteria :

Patients > 18 years with any subtype of pathologically proven (biopsy or cytology), non-small cell lung cancer. The diagnosis may be established from biopsy or cytology obtained from the primary tumor and/ or from metastatic lymph nodes.

Minimal diameter of the primary tumor 4 cm, this to allow for boosting of sub-volumes.

UICC Stage T2-4, N0-3, M0 disease (TNM definition see appendix 2).

Only stage IB-II patients who are nog candidates for surgery are study candidates.

Measurable disease at registration.

ECOG-performance status ≤ 2 (see appendix 6)

Lung function: FEV1 and DLCO at least 40 % of the age-adjusted normal value

Willing and able to give a written informed consent.

Patients with locoregional recurrent lung tumor following surgery or a second primary cancer (at least 3 years after treatment) are eligible, unless a pneumonectomy was performed.

SUVmax in the pre-treatment FDG-PET scan ≥ 5 for the primary tumor.

Adequate organ function, including the following:

Adequate bone marrow reserve: absolute neutrophil (segmented and bands) count (ANC) ≥ 1.5 x 109/L, platelets ≥ 100 x 109/L, and hemoglobin ≥ 9 g/dL.

Hepatic: bilirubin ≤ 1.5 times the upper limit of normal (x ULN); alkaline phosphatase (AP), aspartate aminotransferase (ASAT), and alanine aminotransferase (ALAT) ≤ 3.0 x ULN (AP, AST, and ALT ≤ 5 x ULN is acceptable if liver has tumor involvement).

Renal: calculated creatinine clearance (CrCl) ≥ 45 ml/min based on the original weight based Cockcroft and Gault formula

For women: Must be surgically sterile, postmenopausal, or compliant with a highly reliable contraceptive method (failure rate <1%) during and for 6 months after the treatment period; must have a negative serum or urine pregnancy test within 7 days before study enrollment and must not be breast-feeding.

For men: Must during chemotherapy take adequate contraceptive measures.

Exclusion criteria :

Prior radiotherapy to the thorax.

Clinical superior vena cava syndrome, malignant pleural effusion or malignant pericardial effusion.

Tumor growth in large blood vessels on spiral CT scan (encasement is eligible).

T4 because of multiple nodules in the same or ipsilateral lobe(s).

Post-obstructive atelectasis or infiltration that cannot be distinguished from tumor on a CT-PET scan.

Patients with a diagnosis of other cancer within the last 3-years (except in situ carcinoma's and / or non-melanoma skin cancer).

Patients taking non-steroidal anti-inflammatory drugs (NSAID) or acetylsalicylic acid may not receive pemetrexed.

Pregnant women, lactating women