PHASE III STUDY COMPARING POST-OPERATIVE CONFORMAL RADIOTHERAPY TO NO POST-OPERATIVE RADIOTHERAPY IN PATIENTS WITH COMPLETELY RESECTED NON-SMALL CELL LUNG CANCER AND MEDIASTINAL N2 INVOLVEMENT

“Etude Lung ART”
Sponsor : Institut de Cancérologie Gustave Roussy (IGR)

CONTACTS AUX HUG : Service de Radio-oncologie

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DESIGN DE L’ETUDE

Des patients ayant subi une résection complète de leur NSCLC seront randomisés dans l'un des deux groupes suivants :

- Radiothérapie thoracique adjuvante à la dose de 54 Gy en 27 ou 30 fractions
- Pas de radiothérapie thoracique adjuvante

OBJECTIF DE L’ETUDE

Evaluer si la radiothérapie moderne, dans une situation comme celle de ces patients, peut améliorer l’espérance de vie sans une rechute du cancer et sans provoquer des effets secondaires importants ou irréversibles.

CRITERES D’INCLUSION/EXCLUSION

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<th>Inclusion Criteria</th>
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<tr>
<td>1</td>
<td>Histological evidence of non-small cell lung cancer (NSCLC),</td>
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<td>2</td>
<td>Complete resection by lobectomy, bilobectomy or pneumonectomy (i.e. patients with</td>
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<td>positive margins or extra-capsular extension in a node removed separately in case</td>
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<td>of sampling not to be included)</td>
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<td>3</td>
<td>Mediastinal lymph node exploration (lymph node sampling or systematic dissection of</td>
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<td>lymph nodes at levels 2, 4, and 7, in case of upper/middle right-sided lung cancer;</td>
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<td>4, 7, 8 and 9 in case of lower right sided lung cancer; 5, 6 and 7 in case of upper</td>
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<td>left-sided lung cancer; 7, 8 and 9 in case of lower left-sided lung cancer is</td>
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<td>recommended)</td>
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<td>4</td>
<td>Pathologically or cytologically documented N2 mediastinal nodal involvement, at the</td>
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<td>time of surgery if no preoperative chemotherapy or before preoperative chemotherapy,</td>
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<td>according to the criteria of the joint AJCC and UICC classification. Clinical N2</td>
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<td>patients</td>
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dgn 17.12.2014
without cytological or histological documentation of mediastinal node involvement before preoperative chemotherapy can be included in the study if, and only if, they have histologically confirmed N2 disease at the time of surgery

5 Prior chemotherapy is allowed (pre-operative or post-operative adjuvant chemotherapy, or both)

6 Patient aged ≥18 years

7 Good Performance status (WHO ≤ 1)

8 Adequate pulmonary function with post-operative FEV1 after surgery > 1 l or over 35% theoretical value, PO2 ≥ 70 mmHg, PCO2 < 45 mmHg

9 Information given to patient and signed informed consent form

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### Exclusion Criteria

1 Documented metastases, (except for ipsilateral nodule(s) in a different lobe after pneumonectomy or bi-lobectomy)

2 Major pleural or pericardial effusion

3 Synchronous contra-lateral lung cancer

4 Clinical progression during post-operative chemotherapy

5 Previous chest radiotherapy

6 Intention of concomitant chemotherapy during radiotherapy

7 Weight loss in the previous 6 months before surgery ≥ 10%

8 Evidence of severe or uncontrolled systemic disease as judged by the investigator

9 Recent (< 6 months) severe cardiac disease (arrhythmia, congestive heart failure, infarction, pace-maker) or pulmonary disease

10 Past or current history of neoplasm other than non-small cell lung cancer, diagnosed within the last 5 years, except:
   - basal cell carcinoma of the skin,
   - in situ carcinoma of the cervix,
   A patient diagnosed for another neoplasm 5 years ago or more, treated and considered as cured may be included in the study if all the other criteria are respected

11 Pregnancy or breast feeding or inadequate contraceptive measures during treatment

12 Patients who, for family, social, geographic or psychological reasons, cannot be adequately followed up and/or are incapable of undergoing regular controls

13 Patient deprived of freedom or under guardianship