IFCT-0301 randomized phase II trial of gefitinib, gemcitabine or docetaxel in Performance Status (PS) 2 or 3 advanced non-small cell lung cancer (NSCLC) patients: analysis of the clinical impact of comorbidities and tumour burden.


Background: PS 2 or 3 patients are rarely considered for clinical trials. Optimal treatment in this setting remains challenging. A study by the Intergroupe Francophone de Cancerologie Thoracique (IFCT) showed the main causes of death were related to the tumour burden, and not to toxicity.

Eligibility criteria

- Adequate hematologic, renal and hepatic functions
- PS 2 or 3 patients with confirmed advanced NSCLC were included into a multicenter phase II randomized trial: arm A, gefitinib (PO, 250 mg/day), arm B, gemcitabine (IV, 1250 mg/m², day 1) and arm C, docetaxel (IV, 75 mg/m², day 1, every 3 weeks). Treatments were maintained until progression or unacceptable toxicity. The second-line treatment consisted of: arm A: gefitinib, arm B: gemcitabine and arm C: docetaxel.

Results: Between December 2000 and February 2007, 171 patients were enrolled. Out of the 182 eligible patients, 1 patient died before treatment, 1 was lost to follow-up, 10 were excluded from the analysis (by 7 outside centers; 3 for uncontrolled protocol violation). 157 patients were finally analyzed.

Conclusion: In this study neither comorbidities nor the tumour burden could explain the difference observed between PS 2 and PS 3 patients. The survival data are similar with subgroup data obtained in large randomized trials (all PS).

Discussion

- This study is one of the first randomized trials on PS 2 or 3 patients with advanced NSCLC.
- A challenge. The aim of this study conducted by the Intergroupe Francophone de Cancerologie Thoracique (IFCT) was to evaluate 3 monotherapy modalities and better understand causes for compromised PS.
- In spite of the fragility of the patients, the treatments do not put concerned their life threatening problems in danger.

EICT-Chronic trial centres

- Lyon - CAC
- Longjumeau - CH
- Jonzac - CH
- Colmar - CH
- Briey - CHG
- Vesoul - CHI
- Clamart - Percy
- Bobigny - Avicenne

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