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Articles

Gefitinib plus best supportive care in previously treated patients with refractory advanced non-small-cell lung cancer: results from a randomised, placebo-controlled, multicentre study (Iressa Survival Evaluation in Lung Cancer)

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Summary

Background

This placebo-controlled phase III study investigated the effect on survival of gefitinib as second-line or third-line treatment for patients with locally advanced or metastatic non-small-cell lung cancer.

Methods

1692 patients who were refractory to or intolerant of their latest chemotherapy regimen were randomly assigned in a ratio of two to one either gefitinib (250 mg/day) or placebo, plus best supportive care. The primary endpoint was survival in the overall population of patients and those with adenocarcinoma. The primary analysis of the population for survival was by intention to treat. This study has been submitted for registration with ClinicalTrials.gov, number 1839IL/709.

Findings

1129 patients were assigned gefitinib and 563 placebo. At median follow-up of 7Â·2 months, median survival did not differ significantly between the groups in the overall population (5Â·6 months for gefitinib and 5Â·1 months for placebo; hazard ratio 0Â·89 [95% CI 0Â·77â€“1Â·02], p=0Â·087) or among the 812 patients with adenocarcinoma (6Â·3 months *vs* 5Â·4 months; 0Â·84 [0Â·68â€“1Â·03], p=0Â·089). Preplanned subgroup analyses showed significantly longer survival in the gefitinib group than the placebo group for never-smokers (n=375; 0Â·67 [0Â·49â€“0Â·92], p=0Â·012; median survival 8Â·9 *vs* 6Â·1 months) and patients of Asian origin (n=342; 0Â·66 [0Â·48â€“0Â·91], p=0Â·01; median survival 9Â·5 *vs* 5Â·5 months). Gefitinib was well tolerated, as in previous studies.

Interpretation

Treatment with gefitinib was not associated with significant improvement in survival in either coprimary population. There was pronounced heterogeneity in survival outcomes between groups of patients, with some evidence of benefit among never-smokers and patients of Asian origin.

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