

Summary

Phase II trial with standard chemotherapy and panitumumab in patients with metastatic NSCL selected on the basis of mutational status EudraCT no. 2009-015068-32

The protocol included 23 patients over a period of 3.5 years. Only 19 were evaluable due to toxicity and subsequent treatment discontinuation. At the time of the interim analysis 7 out of the 19 evaluable patients had partial response, which was the threshold for continued enrolment. However, as per 1 June 2013 enrolment was stopped based on the following:

The very low enrolment rate indicated that the patient population was not large enough to continue the study. The next step would include 20 patients, the duration of which would be disproportionately long, since many patients seemed to not meet the inclusion criteria. Also, the results of recent studies have questioned the effect of adding panitumumab to the treatment of this category of patients.

The rate of side effects was too high. Discontinuation of panitumumab was required in 4 out of 23 patients (17.5%) and many experienced toxicity to an extent requiring dose reduction or supportive treatment.

The results of the study could not form the basis of a journal article but were presented at an oral PhD defense session.