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Capecitabine and cisplatin with or without cetuximab for patients with previously untreated advanced gastric cancer (EXPAND): a randomised, open-label phase 3 trial.

Patients with advanced gastric cancer have a poor prognosis and few efficacious treatment options. We aimed to assess the addition of cetuximab to capecitabine-cisplatin chemotherapy in patients with advanced gastric or gastro-oesophageal junction cancer. In our open-label, randomised phase 3 trial (EXPAND), we enrolled adults aged 18 years or older with histologically confirmed locally advanced unresectable (M0) or metastatic (M1) adenocarcinoma of the stomach or gastro-oesophageal junction. We enrolled patients at 164 sites (teaching hospitals and clinics) in 25 countries, and randomly assigned eligible participants (1:1) to receive first-line chemotherapy with or without cetuximab. Randomisation was done with a permuted block randomisation procedure (variable block size), stratified by disease stage (M0 vs M1), previous oesophagectomy or gastrectomy (yes vs no), and previous (neo)adjuvant (radio)chemotherapy (yes vs no). Treatment consisted of 3-week cycles of twice-daily capecitabine 1000 mg/m² (on days 1-14) and intravenous cisplatin 80 mg/m² (on day 1), with or without weekly cetuximab (400 mg/m² initial infusion on day 1 followed by 250 mg/m² per week thereafter). The primary endpoint was progression-free survival (PFS), assessed by a masked independent review committee in the intention-to-treat population. We assessed safety in all patients who received at least one dose of study drug. This study is registered at EudraCT, number 2007-004219-75. Between June 30, 2008, and Dec 15, 2010, we enrolled 904 patients. Median PFS for 455 patients allocated capecitabine-cisplatin plus cetuximab was 4.4 months (95% CI 4.2-5.5) compared with 5.6 months (5.1-5.7) for 449 patients who were allocated to receive capecitabine-cisplatin alone (hazard ratio 1.09, 95% CI 0.92-1.29; p=0.32). 369 (83%) of 446 patients in the chemotherapy plus cetuximab group and 337 (77%) of 436 patients in the chemotherapy group had grade 3-4 adverse events, including grade 3-4 diarrhoea, hypokalaemia, hypomagnesaemia, rash, and hand-foot syndrome. Grade 3-4 neutropenia was more common in controls than in patients who received cetuximab. Incidence of grade 3-4 skin reactions and acne-like rash was substantially higher in the cetuximab-containing regimen than in the control regimen. 239 (54%) of 446 in the cetuximab group and 194 (44%) of 436 in the control group had any grade of serious adverse event. Addition of cetuximab to capecitabine-cisplatin provided no additional benefit to chemotherapy alone in the first-line treatment of advanced gastric cancer in our trial. Merck KGaA.
Occurences:
  - Einrichtungen > Fakultäten > Fakultät für Medizin > Kliniken und Institute > III. Medizinische Klinik und Poliklinik (Hämatologie / Onkologie) > 2013

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