

Study shows new second line therapy for metastatic colorectal cancer is effective and safe

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A randomised trial in 650 patients has confirmed the safety and efficacy of a new second line treatment for metastatic colorectal cancer, researchers report at the ESMO Asia 2017 Congress.

Oral fluorinated pyrimidines have been investigated to replace intravenous 5FU in colorectal cancer (CRC). Capecitabine combined with oxaliplatin (XELOX) has demonstrated comparable efficacy and safety to FOLFOX for the management of metastatic and adjuvant CRC. However, the combined capecitabine and irinotecan (XELIRI) regimen failed to replace FOLFIRI due to concerns over safety and efficacy.

A modified XELIRI (mXELIRI) regimen was subsequently developed with reduced doses of irinotecan (200 mg/m² on day 1) and capecitabine (1600 mg/m² on days 1–14). In combination with bevacizumab it has shown favourable tolerability and efficacy comparable to XELOX plus bevacizumab in the first and second line settings. (3,4)

Following these two trials, the Asian XELIRI Project (AXEPT) was designed. This multicentre, open-label, randomised phase 3 trial assessed the efficacy and safety of mXELIRI versus FOLFIRI, with or without bevacizumab, as second line treatment for [patients](#) with metastatic CRC. It was designed to demonstrate non-inferiority of the capecitabine containing regimen in terms of overall survival, with 95 percent

confidence interval (CI) upper limit of the hazard ratio (HR) pre-specified as less than 1.3.

The trial enrolled 650 patients aged 20 years or older with histologically confirmed unresectable colorectal adenocarcinoma. Patients had been withdrawn from first line chemotherapy for mCRC due to intolerable toxicity, disease progression or relapse fewer than 180 days after the final dose of adjuvant chemotherapy. Patients were randomly assigned in a 1:1 ratio to receive either mXELIRI with or without bevacizumab every three weeks or FOLFIRI with or without bevacizumab every two weeks.

Patients were stratified according to the following factors: (1) country (Japan versus South Korea versus China), (2) Eastern Cooperative Oncology Group (ECOG) performance status (0–1 versus 2), (3) number of metastatic sites (one versus more than one), (4) prior oxaliplatin treatment (yes versus no), and (5) concurrent bevacizumab treatment (with versus without).

After a median follow-up of 15.8 months, the median overall survival was 16.8 and 15.4 months in the mXELIRI and FOLFIRI arms, respectively (HR 0.85, 95 percent CI 0.71–1.02, non-inferiority test p

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