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**A multicenter phase III trial comparing irinotecan-gemcitabine (IG) with gemcitabine (G) monotherapy as first-line treatment in patients with locally advanced or metastatic pancreatic cancer.**

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**Source**

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**Abstract**

Our purpose was to determine the response rate and median and overall survival of gemcitabine as monotherapy versus gemcitabine plus irinotecan in advanced or metastatic pancreatic cancer. Patients with histologically or cytologically confirmed adenocarcinoma who were chemotherapy and radiotherapy naive were enrolled. Patients were centrally randomised at a one-to-one ratio to receive either gemcitabine monotherapy (900 mg m<sup>-2</sup>) on days 1, 8 and 15 every 4 weeks (arm G), or gemcitabine (days 1 and 8) plus irinotecan (300 mg m<sup>-2</sup>) on day 8 (arm IG), repeated every 3 weeks. The total number of cycles administered was 255 in the IG arm and 245 in the G arm; the median number of cycles was 3. In all, 145 patients (71 in arm IG and 74 in arm G) were enrolled; 60 and 70 patients from arms IG and G, respectively, were evaluable. A complete clinical response was achieved in three (4.3%) arm G patients; nine (15%) patients in arm IG and four (5.7%) in arm G achieved a partial response. The overall response rate was: arm IG 15% and arm G 10% (95% CI 5.96-24.04 and 95% CI 2.97-17.03, respectively; P=0.387). The median time to tumour progression was 2.8 months and 2.9 months and median survival time was 6.4 and 6.5 months for the IG and G arms, respectively. One-year survival was 24.3% for the IG arm and 21.8% for the G arm. No statistically significant difference was observed comparing gemcitabine monotherapy versus gemcitabine plus irinotecan in the treatment of advanced pancreatic cancer, with respect to overall and 1-year survival.