Fluorouracil plasma monitoring: systematic review and economic evaluation of the My5-FU assay for guiding dose adjustment in patients receiving fluorouracil chemotherapy by continuous infusion

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Plain English summary

The My5-FU assay for guiding dose adjustment

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Plain English summary

The My5-FU test kit is designed to measure the amount of 5-fluorouracil (5-FU) circulating in the blood using a blood sample taken during the 5-FU infusion. 5-FU is a chemotherapy used in colorectal, head and neck (H&N) and other cancers. Knowing the individual patient's level of 5-FU allows doctors to adjust the dose more precisely for the individual thus improving dosing and avoiding side effects. My5-FU is manufactured by Saladax Biomedical Inc. (PA, USA) and can be used with patients who have various types of cancer. We aimed to examine the clinical effectiveness and cost-effectiveness of 5-FU plasma monitoring with the My5-FU assay.

We undertook systematic reviews between January and April 2014 and developed a cost-effectiveness model. As My5-FU has not been employed in good-quality studies that report patient outcomes, we had to use studies that used methods other than My5-FU and had to assume equivalence between methods.

We included 35 and 54 studies in the clinical effectiveness and cost-effectiveness reviews respectively. The quality and quantity of evidence was very weak. Survival appeared to be improved by between 5 and 7 months for patients with metastatic colorectal cancer (mCRC), but the evidence for this was weak and extremely patchy.

Cost-effectiveness models were developed for both mCRC and H&N cancer. We estimated the cost per test of My5-FU to be £61.03. We found that with reported improvements My5-FU was likely to be cost-effective at standard levels of willingness to pay for both mCRC and H&N cancer.

We considered that considerable uncertainties remain about evidence quality and practical implementation of My5-FU and that well-conducted randomised controlled trials are needed.

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