TACTIC: Phase 2 trial of panitumumab, cisplatin and gemcitabine in biliary tract cancer

The TACTIC trial is helping researchers answer an important health question. It is providing evidence on whether panitumumab (Vectibix), an antibody treatment, benefits patients with advanced cancer of the biliary tract (or bile ducts) with a specific gene type.

We appreciate the part played by our volunteer participants. This trial may help to improve the medical treatment of patients in the future. Here is a summary of the trial and results.

What was the trial about?

This was a phase 2 trial, meaning that it was a small trial exploring whether a new treatment is safe and effective enough to continue with more research on it.

The investigators started with the knowledge that adding antibody treatments to chemotherapy appeared to increase the number of cancers shrinking. They also knew that where other cancers were concerned, improvement was related to a gene type, *KRAS* wild-type. The trial question was whether selecting patients for the trial by this gene type would lead to a reasonable benefit.

78 patients with advanced biliary tract cancer had their tumours tested for the *KRAS* wild-type gene. 48 of them had this gene type, so were eligible to enrol in the trial. Of these, 36 had cancer that had spread to other organs.

All patients had the same treatment: standard chemotherapy with infusions of cisplatin and gemcitabine on two days every 3 weeks and also panitumumab on one of those days.

The treatment was continued until it was no longer effective (when the tumour started growing again). It was stopped if any of the treatments was causing harm or if the patient or doctor decided to stop it.

How was the effect of treatment measured?

During the trial, the size of the tumour was measured from scans, and changes were noted. These were classified as complete response (all visible tumour disappeared), partial response (at least 30% of the tumour disappeared), or stable disease. The treatment was considered to have benefited a patient if scans at 12 weeks showed that the tumour had not enlarged.

Other important measures were progression-free survival—that is, the time between the participant's entry into the trial until the disease became worse—and overall survival.

Adverse events—that is, symptoms and abnormal test results that may or may not have been related to the treatment—were recorded and classified. The patients' quality of life was also assessed by a questionnaire every 3 weeks. The standard questionnaire for cancer patients covers areas like pain, and physical, social and emotional issues.

Was the new treatment effective?

When assessed at 12 weeks into the trial, 80% of the tumours had not grown during the treatment. The investigators considered that the treatment acts against this type of tumour and is worthy of ongoing investigation.

The average survival was only about a year, although some patients survived up to 3 years. The average progression-free survival was several months. The disease had become worse in all patients by 2 years.

What were the side-effects of the treatment?

Many patients (98%) had mild anaemia, rashes, infections, fatigue, and blood electrolyte disturbance (hypomagnesaemia). Some had vomiting or diarrhoea.

Were there any serious side-effects?

Three-quarters of the patients had a disorder or illness that required hospital treatment. These events were expected for very ill cancer patients having this kind of treatment.

The most common problems were abnormal blood counts and infections. Three patients discontinued one of the standard chemotherapy drugs and 5 patients discontinued both of them because of adverse effects. One patient died, and this was thought to be because of the chemotherapy. The antibody treatment, panitumumab, did not have to be discontinued permanently by any of the patients.

What does this mean for trial patients?

Patients with advanced biliary tract cancer generally have a poor prognosis. Patients in this trial had on average 8 months when their disease improved or did not get worse.

How will the results help patients and doctors in future?

TACTIC has shown that panitumumab with standard chemotherapy appears to have some effect on the growth of biliary tract cancers with a specific gene type. Further research is required to see if selection of patients based on more gene characteristics may improve the outcomes.

What will the researchers do next?

The blood samples and tumour tissue provided by patients will be used, with their permission, to look for individual biological differences that might have affected a patient's progress.

The investigators are still analysing the results of the quality-of-life questionnaires. Quality-of-life in this small trial was mainly exploratory. The data from so few patients will be limited.

Where can I find out more about the trial?

Talk with your GP or oncologist.

The results have been published in a scientific journal

Ferraro D, and others. TACTIC: a multicentre, open-label, single-arm phase II trial of panitumumab, cisplatin, and gemcitabine in biliary tract cancer. *Cancer Chemotherapy and Pharmacology.* Published online 24 Jun 2016. The article is only available on purchase from the journal, but a summary is available here.

Trial registration

Australian New Zealand Clinical Trials Registry
www.anzctr.org.au

Registered number ACTRN12611000245998

AGITG

Read about the trial here.

Australian Cancer Trials

www.australiancancertrials.gov.au

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Results of any clinical trial do not represent complete knowledge about treatment. Patients should not change their therapy on their understanding of the results.