ASCOLT Lay Summary

Study Background

Colorectal cancer is a very common cancer in Australia and worldwide. Currently the standard therapy for patients with localised colorectal cancer (that is, a cancer that has started in the bowel but hasn’t spread to other organs) is surgery to completely remove the tumour and lymph nodes. In some patients the surgery shows evidence of cancer cells in the lymph nodes (Stage 3 colorectal cancer), or the lymph nodes may not contain cancer cells but there are other features of the cancer that make it a higher risk of coming back in the future (high risk Stage 2 cancer). In these cases, surgery is usually followed by chemotherapy to decrease the risk of the cancer coming back. Despite having this extra treatment, unfortunately a significant number of patients still have recurrence of their disease. When the cancer comes back, it is usually not able to be cured.

Rationale for the study

Aspirin is known to be helpful in preventing and treating heart and blood vessel diseases. There is growing evidence that aspirin also has some anticancer properties as well. Studies that have looked at large groups of patients with colorectal cancer suggest that aspirin might be able to reduce recurrence of the cancer and improve survival in patients with localised colorectal cancer. However these findings need to be confirmed by information from randomised clinical trials before treatment with aspirin can be considered standard therapy for this group of patients. Investigating the role of aspirin in colorectal cancer patients was chosen as the highest priority by Australian consumers, clinicians and researchers at a national forum in August 2011.

The ASCOLT study will provide proof of the role of aspirin in patients with localised colorectal cancer and will set a new standard nationally and internationally. As aspirin is cheap, readily available and familiar to most people, any impact on increased survival is likely to result in it being widely used as a cheap and cost effective agent.

Study Aim

The aim of the study is to determine if aspirin improves disease free survival and overall survival in patients with resected high risk stage II and III colorectal cancer.

Proposed study design

The ASCOLT study is an international, multi-centre, double blinded, randomised phase 3 trial. ASCOLT is being centrally coordinated by the National Cancer Centre Singapore and locally coordinated by the AGITG in collaboration with the NHMRC Clinical Trials Centre (CTC). About 1200 patients will be required. It is expected that 200 patients will be recruited in Australia.

The trial will be run at more than 20 specialist Australian and New Zealand sites. Recruitment is expected to take about 24 months.

After given written informed consent patients will be randomised to receive either 200 mg aspirin tablets or 200 mg matching placebo tablets once a day for 3 years. Patients will be followed up for an extra two years.

Restrictions to the study

To be able to take part in this trial, patients must have had surgery to remove their cancer, and have high risk stage II or stage III colorectal cancer. They must also have finished having any other adjuvant (extra) treatment such as chemotherapy or radiotherapy. Patients with other serious illnesses or who are very unwell will not be suitable for the study, nor will patients already on aspirin for other reasons.
Study visits and required tests (in addition to those which form part of standard care)

After randomisation patients will have standard follow up assessments for colorectal cancer according to international guidelines. This includes 3 monthly assessments for 3 years followed by 6 monthly assessments for an extra 2 years. These assessments include clinical examination, assessments for side effects of previous and current treatments, blood tests and a total of 2 colonoscopies in 5 years. There are no additional tests or follow up visits required for trial participants.

Quality of life issues

Side effects that occasionally occur with aspirin are gastrointestinal disorders such as nausea, vomiting, and diarrhoea. Gastrointestinal ulcers may rarely develop, and these can occasionally cause bleeding or a hole to develop in the stomach. The risk of having significant bleeding is usually very small – it occurs in around 3 to 12 people in every 10000 who are taking aspirin, each year. Rarely, patients can have allergies to aspirin which can cause difficulty in breathing or skin reactions. There have been a few cases of liver or kidney abnormalities, or severe skin problems, related to using aspirin.

Given the fact that aspirin is such a well established drug with a well known list of side effects, specific quality of life questionnaires were not included in the ASCOLT trial. However all adverse events or side effects will be reported.

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