# ALaCaRT: Australasian Laparoscopic Cancer of the Rectum trial

The ALaCaRT trial is helping researchers answer an important health question for patients. It has provided evidence on whether laparoscopic (or keyhole) surgery is an alternative to open surgery for rectal cancer.

We appreciate the contribution made by volunteer participants. This 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?

Laparoscopic surgery is being used more and more for abdominal operations. Many cancers can be removed through very small incisions, allowing patients to recover quickly. However, removing a tumour from the rectum is more complex, and it is more difficult for the surgeon to be sure of completely removing the tumour. Laparoscopic surgery has many obvious benefits, so this trial was important to make sure that it was not worse than open surgery in terms of treating the cancer.

The trial question was whether laparoscopic, or keyhole, surgery is as good as traditional open surgery for total mesorectal excision, that is, removal of a tumour of the rectum and part of the bowel surrounding the tumour.

### Eligible patients

The trial had 475 patients from 24 hospitals in Australia and New Zealand. Patients were randomly allocated to laparoscopic or open surgery. Patients had tumours within 15 cm of their anus.

### Quality of the surgery

At the time of the operation, surgeons could change from the allocated procedure to the other method according to their judgment.

Great care was taken to ensure that surgeons were experienced and competent in these operations. Surgeons applying to take part in the trial had to provide a video of an operation and a log book recording at least 100 bowel cancer operations and 30 rectal cancer operations.

## How was the effect of treatment measured?

The operation was considered a success if the tumour was completely removed and at least 1 mm of the edges of the tissue removed were clear of any tumour. This was assessed under a microscope by a pathologist who had no knowledge of the type of operation the patient had received.

## Was the new treatment better?

This trial was not testing whether the new treatment was better, but rather whether it was no worse than the traditional treatment. Therefore, it was a non-inferiority trial.

On this question, the outcome was not clear-cut. The trial showed that non-inferiority was not ruled out. That is, open surgery could be better. The tumour was completely or almost completely removed in 97% of the laparoscopic surgery group and 99% of the open surgery group. The margin around the tumour was completely clear in 93% of patients in the laparoscopic group and 97% of those having open surgery.

Some characteristics of patients were examined in detail—such as whether they had radiotherapy before the operation, whether they were obese, and how advanced their cancer was. These characteristics did not make a significant difference. Patients who have had radiotherapy, who are obese, or who have more advanced cancers are advised that they may do better having the open surgery.

## What were the complications?

There were low rates of complications and relatively few changes from a laparoscopic operation to an open procedure. In almost all cases, where the surgeons planned to preserve the anal sphincter to ensure ongoing bowel evacuation, they succeeded.

There were no differences between the two surgery groups in complications, pain, return of bowel function. or the length of stay in intensive care or in hospital. Small percentages (less than 10%) of patients had problems after the surgery, such as a delayed return to normal bowel function, fever, bleeding and leaks, requiring medical attention.

### Were there any serious side-effects?

In both groups there were very low rates of serious complications from the surgery. Two patients who had open surgery and one who had laparoscopic surgery died from complications within a month of their surgery. This is unfortunately expected with this form of cancer.

## What does this mean for trial patients?

Patients can be reassured that the quality of surgery for both groups of patients was high. A quarter of the patients were obese and many overweight, which makes the operation more challenging.

The overall success rate was good, as was the low rate of patients needing a pouch to replace the bowel opening.

## What will the researchers do next?

The main criteria for choosing laparoscopic surgery for rectal cancer relate to how patients fare over the longer term. Trial patients will be followed up with clinic visits and tests for 5 years to assess the effect of the surgery on recurrence of the cancer, survival and other outcomes. Results will be published by 2020. In addition, quality of life will be assessed after all participants have had 12 months of follow-up.

## How will the results help patients and doctors in future?

Surgeons all over the world will be able to use the evidence from this and similar trials to decide whether patients should have laparoscopic or open surgery. Because the results have shown that , in some cases, laparoscopic surgery may not remove the tumour as effectively as open surgery, they will be cautious in their choices.

## Where can I find out more about the trial?

Talk with your GP or oncologist.

### The results have been published in a scientific journal

Stevenson, ARL, and others. Effect of laparoscopic-assisted resection vs open resection on pathological outcomes in rectal cancer: the ALaCaRT randomized clinical trial. *JAMA* 2015; volume 314, issue 13: pages 1356–1363.

### Trial registration

Australian New Zealand Clinical Trials Registry

www.anzctr.org
Search for number ACTRN12609000663257

### Australasian Gastro-Intestinal Trials Group (AGITG)

agitg.org.au/clinical-trials/trials-in-follow-up/1-a-la-cart/

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None of the investigators have any conflicts of interest.

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