

ICON7

Bevacizumab in Ovarian Cancer



This information has been prepared for patients, their relatives, doctors and nurses involved in the ICON7 trial.

First results of the ICON7 trial – Does the addition of bevacizumab to standard chemotherapy delay the progression of disease in women with ovarian cancer?

In 2006 the Medical Research Council launched a trial called ICON7. It looked at the addition of a drug called bevacizumab to standard chemotherapy for women with ovarian cancer. This information tells you about the results of this trial.

Bevacizumab (also known by its brand name Avastin) is a ‘targeted therapy’ that works by blocking the development of new blood vessels and interfering with the tumour’s ability to grow and spread to other parts of the body. In a number of cancers the addition of bevacizumab to chemotherapy has been shown to improve outcomes. ICON7 aimed to find out if this was also the case in ovarian cancer.

Between December 2006 and February 2009 1528 women were randomised into the trial from Europe, Canada, Australia and New Zealand. Following diagnosis of their disease and surgery to remove it the women were put into one of two groups:

- Women in one group received standard chemotherapy with carboplatin and paclitaxel every 3 weeks for 6 cycles of treatment and no other treatment

OR

- In the other group, women received standard chemotherapy with carboplatin and paclitaxel every 3 weeks for 6 cycles of treatment. Bevacizumab was also given at the start of each chemotherapy treatment. Following this, bevacizumab was given alone every 3 weeks for a further 12 cycles.

Researchers did not choose which group a woman went in to – this was done by a computer, to make sure that each group of women was as similar as possible. This helped to ensure that the results of this trial were as reliable as they could possibly be. Following the completion of their treatment all women were followed within the trial with routine clinical examination and CT scans at regular intervals, they were also asked to complete Quality of Life questionnaires.

What were the results?

Researchers looked at information on when women in the trial had progression of their ovarian cancer shown on CT scan, and looked to see if there was a difference in the time taken for the disease to come back in those women who received bevacizumab and those who didn't.

The results of the ICON7 trial were positive. The addition of bevacizumab to standard chemotherapy resulted in an improvement in progression free survival (time without disease worsening or coming back). The effect of bevacizumab was most striking after one year when 15% fewer women treated with bevacizumab had developed progression of disease than women who had not received bevacizumab. The beneficial effect of bevacizumab reduced over time and overall, women in the trial who received bevacizumab experienced an average of 1.5 months of extra time without the disease worsening.

On the whole bevacizumab treatment was well tolerated and no new side effects were identified. The most common side effect was high blood pressure, with 18% of women in the bevacizumab arm having high blood pressure at a level which may have required treatment with tablets, compared with 2% in the standard chemotherapy arm. High blood pressure was easily monitored and treated in the trial.

This is the second positive trial with bevacizumab in ovarian cancer, the results of ICON7 support the findings of an American trial of bevacizumab (GOG218) that were announced in June of this year. Bevacizumab is the first new drug that has improved outcomes for women with ovarian cancer in over 17 years.

The period of extra time before the disease progresses is shorter than we hoped, but we know from experience that cancer treatment improves over the years by a series of small advances like this one.

Women are still being followed in the trial and it will be important to see longer term results of the effect of bevacizumab on progression free survival and to see if overall survival is increased. These results should be available in 2012. Analysis of the information collected in the trial from Quality of Life questionnaires will also be important in determining women's experience of receiving bevacizumab infusions.

Analysis of tissue samples and blood samples taken during the trial may also help us to identify groups of patients who benefit more from bevacizumab. This will help us to design future trials and studies and help us understand the best way to use this new treatment.

More information

The doctor or nurse who gave you this letter will be able to explain the results in more detail and answer any questions you may have. First results of the trial have just been announced at an international conference for cancer researchers (the European Society for Medical Oncology). You can read

more about this conference here <http://www.esmo.org>. The results will also be published in a scientific journal. We will tell your doctor or nurse when the results are published and they should be able to give you a copy if you would like one.

Nurses at Ovacome (www.ovacome.org.uk) can also help you understand this research. You can call them on the Ovacome helpline 0845 371 0554

Thank you

On behalf of all the ICON7 researchers, we would like to thank all of the women who took part in this research, and the families who supported them. Cancer treatment could not be improved without the support of many people who take part in cancer research every year.