

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

Updated results from the ICON7 trial – combining bevacizumab with standard chemotherapy delays the progression of disease in women with ovarian cancer and may improve overall survival in women at high risk of recurrence

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

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 several types of cancer, combining bevacizumab with chemotherapy has been shown to improve the effectiveness of treatment. ICON7 aimed to find out if this was also the case in ovarian cancer.

Between December 2006 and February 2009 1528 women from Europe, Canada, Australia and New Zealand were randomised into the trial. Following diagnosis of their disease and surgery to remove cancerous cells, 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 until their disease got worse

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 the group into which a woman went – this was done by a computer, to make sure that the two groups of women were as similar as possible. This helped to ensure that the results of the trial were as reliable as possible. After completing their treatment, all women in the trial were followed with routine clinical examination and CT scans at regular

intervals. They were also asked to complete questionnaires about their quality of life.

What were the results?

Researchers looked at information on when women in the trial had progression of their ovarian cancer shown on a 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 compared with those who did not.

The first results from the ICON7 trial were announced in 2010. The results were positive, showing that combining bevacizumab with standard chemotherapy improves progression-free survival (time without disease worsening or coming back). The effect of bevacizumab was most striking after 1 year, when disease progression had occurred in 15% fewer women treated with bevacizumab than without bevacizumab. Overall, women in the trial who received bevacizumab experienced an average of 1.5 months of extra time without the disease worsening. The effect seemed to be more pronounced in women who had a higher chance of their disease coming back.

The ICON7 trial is also aiming to find out whether women who receive bevacizumab live for longer than those in the group receiving no bevacizumab. The overall survival results presented in 2010 showed no clear difference between the bevacizumab and no bevacizumab groups. Final results are expected in 2013 but, regulatory authorities who are considering licensing bevacizumab for the treatment of ovarian cancer asked researchers to look early to make sure that bevacizumab was not causing problems. The updated results showed that the improvement in progression-free survival still exists and improvement in overall survival in favour of the group treated with bevacizumab, continues to be seen. It also seems as though patients most likely to have early disease progression (high-risk disease) have a more noticeable improvement in survival than women with lower-risk disease.

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 also announced in 2010. Bevacizumab is the first new drug that has improved outcomes for women with untreated ovarian cancer in 17 years. Very recently, a third trial has shown positive results with bevacizumab in ovarian cancer, this time in patients who have already received chemotherapy after surgery.

Women are still being followed in the trial and it will be important to see final results of the effect of bevacizumab on progression-free survival and to see if overall survival is increased. These results should be available in 2013. 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 tumour tissue and blood samples collected 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 were announced at an international conference for cancer researchers (the European Society for Medical Oncology in 2010; <http://www.esmo.org>) and the recently updated results have just been presented at another international conference in America (the American Society for Clinical Oncology; www.asco.org). You can read more about these conferences on their websites. 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.