Six months of Herceptin could be as effective as 12 months for some women with HER2 positive breast cancer

May 17 2018

For women with HER2 positive early-stage breast cancer taking Herceptin for six months could be as effective as 12 months in preventing relapse and death, and can reduce side effects, finds new research.

The PERSEPHONE trial, a £2.6 million study which incorporated University of Warwick expertise, recruited more than 4,000 women and compared a six month course of treatment of Herceptin with the current standard of 12 months for women with HER2-positive early-stage breast cancer. Funded by the National Institute for Health Research (NIHR) with translational research funded by Cancer Research UK, this is the largest trial of its kind examining the impact of shortening the duration of Herceptin treatment.

The trial, which involved Warwick Clinical Trials, Warwick Medical School and was led by the University of Cambridge found that 89.4% of patients taking six months treatment were free of disease after four years compared with 89.8% of patients taking treatment for 12 months. These results show that taking Herceptin for six months is as effective as 12 months for many women. In addition, only 4% of women in the six month arm stopped taking the drug early because of heart problems, compared with 8% in the 12 month arm. Women also received chemotherapy (anthracycline-based, taxane-based or a combination of both) while enrolled in the trial.

Professor Janet Dunn, Deputy Director of Warwick Clinical Trials Unit, Warwick Medical School, said: "This is a very exciting result and we are delighted that Warwick Clinical Trials at Warwick Medical School was involved.

"There is still further research to be done, however there is now the possibility that women will now avoid longer treatment and the subsequent unnecessary side effects without losing any benefit. It is also good news for the NHS as a shorter duration of medication should help save vital funds."

Herceptin, has been a major breakthrough, prolonging and saving the lives of women with breast cancers that carry the HER2 receptor on the surface of their cancer cells. Around 15 out of every 100 women with early breast cancers have HER2 positive disease.

Herceptin is a targeted therapy that works by attaching to the HER2 receptors preventing the cancer cells from growing and dividing. It has rapidly become standard of care and based on clinical research a 12 month treatment course was adopted. Lead study author Professor Helena Earl, Professor of Clinical Cancer Medicine, University of Cambridge and Cancer Research UK Cambridge Centre, said: "The PERSEPHONE trials team, patient advocates who have worked with us on the study and our investigators are very excited by these results. We are confident that this will mark the first steps towards a reduction of Herceptin treatment to six months in many women with HER2-positive breast cancer. However, any proposed reduction in effective cancer treatment will always be complex and very challenging, and women currently taking the medication should not change their treatment without seeking advice from their doctor. There is more research to be done to define as precisely as possible the particular patients who could safely reduce their treatment duration. We are poised to do important translational research analysing blood and tissue samples collected within

the trial to look for biomarkers to identify subgroups of different risk where shorter/longer durations might be tailored."

Professor Hywel Williams, Director of the NIHR Health Technology Assessment Programme that funded the PERSEPHONE study said: "This is a hugely important clinical trial that shows that more is not always better. Women will now have the potential to avoid unnecessary side effects of longer treatment without losing any benefit. In turn, this should help save vital funds for the NHS and prompt more studies in other situations where the optimum duration of treatment is not known. It is unlikely that research like this would ever be done by industry, so I am delighted that the NIHR are able to fund valuable research that has a direct impact on patients."

Maggie Wilcox, President of Independent Cancer patients Voice (ICPV) who is the patient lead for the PERSEPHONE trial, said "I am delighted to have been part of this landmark trial which is an important step to reduce the length of treatment whilst not changing effectiveness. Most trials add novel treatments to standard practice whilst this has set out to reduce duration of Herceptin. The collection of the patient reported experiences throughout the trial will greatly inform future practice and benefit patients. ICPV is working with the Persephone team to help disseminate these exciting results'.

Case Study—Sarah Stewart-Brown

In 2008 Sarah Stewart-Brown, Professor of Public Health at the University of Warwick's Warwick Medical School was diagnosed with breast cancer. She was told she had a tumour more than two centimetre in size and it was HER2 positive. This means the tumour had a higher than normal level of the protein HER2 on its surface, which stimulates tumours to grow. As a result one of the treatments she was advised to undergo was Herceptin which is designed to target and interfere with the

processes in the cells that cause cancer. The tumour could have spread elsewhere but Sarah was lucky because there was no visible spread to her lymph nodes.

Professor Stewart-Brown underwent an operation to remove the tumour and was prescribed Herceptin. This was administered intravenously which meant a half-day visit to hospital every three weeks and this would have to continue for 12 months.

However three doses (nine weeks) into the treatment Sarah decided to stop her medication; she was developing allergy symptoms, which is a reported side effect of Herceptin, and after careful consideration of the research on Herceptin she started to question if the treatment was doing her more harm than good. She was offered steroids to dampen the allergy symptoms but she refused the medication.

She said: "As a medical professional with years of experience I was very aware that my body need to be working well to mount its own defence against the cancer and it wasn't reacting well to Herceptin. However I did take the hormone blocker Arimidex because my tumour was hormone sensitive and lowering the level of oestrogen can stop or slow the growth of these breast cancers."

"My cancer was an important life event for me in many positive ways. It started making me more aware of my health and the need to look after it. I started to take more notice of my digestive system and was careful to eat what suited me; I started to tackle my high stress levels and now practise mindfulness and various mindful movements like Qi Going. Until this point I had been less careful about my health and hadn't realised that my body needed me to take more care of it."

I didn't take the decision to reduce my Herceptin treatment lightly and wouldn't advise anyone to do so without understanding the pros and

cons. However I believe, and there is research evidence to back this, that beginning to look after yourself better is a very important factor in not just surviving but thriving after cancer. "

Studies that set out to reduce the amount and length of treatment are welcome. Persephone is one such study carried out at the Warwick Clinical Trials Unit at the University of Warwick that has shown that six months of Herceptin is as good as 12 months for those patients entered into the trial.

Sarah said: "I am delighted that the University of Warwick has carried out this important trial jointly with the University of Cambridge. Trials like Persephone are challenging but extremely important to patients and necessary to channel resources more efficiently within the NHS".

More information: PERSEPHONE—duration of trastuzumab study with chemotherapy in early breast cancer: six versus twelve months. www.journalslibrary.nihr.ac.uk … ammes/hta/0630398/#/

Provided by University of Warwick

Citation: Six months of Herceptin could be as effective as 12 months for some women with HER2 positive breast cancer (2018, May 17) retrieved 18 July 2024 from https://medicalxpress.com/news/2018-05-months-herceptin-effective-women-her2.html

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