Six versus 12 months' adjuvant trastuzumab in patients with HER2-positive early breast cancer: the PERSEPHONE non-inferiority RCT

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Plain English summary

The PERSEPHONE RCT

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Plain English summary

The background

There are several different types of breast cancer and some are called 'HER2 positive'. These cancers can often be cured by treatment with chemotherapy and a drug called trastuzumab (also known as Herceptin®; Roche, Basel, Switzerland). Although the first trials of trastuzumab used 12 months treatment, we did not know if less treatment could work as well. A small trial in Finland showed that giving trastuzumab for just 9 weeks was also effective. We know that trastuzumab can have some side effects, including heart problems, so it was important to see if we could reduce the length of treatment time, which is usually 12 months.

What did we do?

We wanted to find out if we could treat patients safely with 6 months rather than 12 months of trastuzumab. We carried out a clinical trial called PERSEPHONE, in which over 4000 patients with this type of early breast cancer took part. Half of the patients were given 12 months of trastuzumab and half were given 6 months of trastuzumab.

What did we find?

We found that the two groups of patients had very similar benefit from treatment. At 4 years after diagnosis 90.3% of those who had received 12 months of trastuzumab were alive and free of any breast cancer recurrence, compared with 89.5% of those who had received 6 months. In other words, 125 patients would need to be treated with 12 months' trastuzumab rather than 6 months' trastuzumab for one more person to be alive and cancer-free 4 years from diagnosis.

The side effects?

Severe side effects of trastuzumab were seen on at least one occasion in 24% of 12-month patients compared with 19% of 6-month patients. More patients receiving 12 months of trastuzumab had to stop trastuzumab early because of heart problems (8% of 12-month patients compared with 3% of 6-month patients).

What does this all mean?

We have shown that 6 months of trastuzumab has similar outcomes to 12 months in treating patients with HER2-positive early breast cancer but with fewer severe side effects, including heart problems, fewer visits to hospital for patients and significant cost savings for the NHS.

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This report

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