



Intensity Modulated and Partial Organ Radiotherapy

The IMPORT LOW Trial (CRUK/06/003)

Main trial results

The IMPORT LOW Trial team would like to thank all participants in the trial.

Background

The aim of the IMPORT LOW trial is to improve radiotherapy treatment for women with early breast cancer. We hope to achieve this by reducing the amount of radiotherapy we give to the whole breast whilst giving the standard amount of radiotherapy to the area close to where the tumour used to be. The trial tests whether doing this preserves the long term physical appearance of women's breasts whilst being just as effective as standard radiotherapy at preventing the cancer returning. It is now several years since the last patient was recruited and we are able to assess the long term side effects of the new radiotherapy treatment.

Between May 2007 and October 2010, 2018 women were recruited into IMPORT LOW following breast conservation surgery. The women were treated at one of 30 UK radiotherapy centres and received radiotherapy in one of three ways:

- **Group 1:** Clinical Standard - Standard radiotherapy to the whole breast
- **Group 2:** Reduced dose radiotherapy - Standard radiotherapy to the area of the breast where the cancer was, and a lower dose of radiotherapy to the rest of the breast.
- **Group 3:** Partial breast radiotherapy - Standard dose of radiotherapy, but only to the area of the breast where the cancer was.

All the women taking part see a specialised health professional at the hospital at specific times after their treatment to assess side effects. About half of the women also had a photograph taken to assess changes to the appearance of their treated breast, and others completed quality of life questionnaires which give patient self assessments. We have now analysed the results from these assessments to see whether or not the cancer has returned in the treated breast (known as local relapse) and assess side effects several years after

radiotherapy. These results were published in a leading international medical journal called The Lancet in August 2017: [http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(17\)31145-5.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(17)31145-5.pdf)

What does the study show so far?

The total number of women whose cancer has come back in the treated breast was very low in all three groups. Most radiotherapy side effects are reported as mild, and the number of women with more severe side effects is very low, according to the photographic assessments.

Overall, IMPORT LOW suggests that reducing the amount of radiotherapy given to the whole breast produces similar results to the standard treatment.

Local relapse:

At five years after radiotherapy local relapse rates are low, around 1%, in all three groups.

Side effects at five years:

- Patients completing the quality of life booklets were asked whether the overall appearance of their affected breast had changed compared with the other side. 15% of those who received partial breast radiotherapy answered quite a bit or very much compared with 27% of those who received the clinical standard whole breast radiotherapy and 20% of those who received reduced dose radiotherapy.
- From the photographs, 18% of patients who received partial breast radiotherapy have a change in breast appearance, compared with 23% who received the clinical standard radiotherapy, and 22% who received reduced dose radiotherapy.
- From the health professionals' assessments, 10% of patients who received either partial breast radiotherapy or reduced dose radiotherapy have moderate or marked side effects, compared with 13% of patients who received the clinical standard radiotherapy.

Each of the assessments above measures slightly different changes that can occur following radiotherapy treatment to the breast. This is why the figures are not the same.

What do these findings mean?

The results are important news for women with early breast cancer. The findings suggest that treating a lower volume of breast tissue with radiotherapy (in the area of the original cancer) is as safe and effective as treating the whole breast with radiotherapy. In addition, side effects from radiotherapy are low in all groups. Stringent statistical tests show that there is a real difference in how patients rate their breast appearance, with those having partial breast radiotherapy rating their breast appearance better than the women in the other groups. The results from the photographs and the health professionals' assessments show that side effects are similarly low in all of the groups. The IMPORT LOW method of partial breast radiotherapy is very simple and could be used easily in many other countries.

What will happen now?

These are the results five years after radiotherapy, but it is important to look at longer-term effects of the treatment as well. We are continuing to follow up as many of the women as we can who entered the IMPORT LOW trial until at least ten years after radiotherapy. We will report on local relapse and side effects again at that point. We also plan to report a more detailed review of results of five-year quality of life outcomes.

If you are taking part in IMPORT LOW and would like further information about the trial please contact your doctor or research nurse at your hospital.

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