

# The PACE Trial

## Main results of the PACE-B trial:

### Is stereotactic body radiotherapy (SBRT) as good as standard radiotherapy?

The PACE-B trial includes 874 men who had prostate cancer at medium-risk of returning after treatment and which had not spread elsewhere in the body. We have been collecting information about people who joined the trial for five years and we now have enough data to be able to share the key findings.<sup>1</sup>

#### ***What is the trial about?***

The aim of the PACE-B trial is to see whether we can improve radiotherapy treatment for men with prostate cancer by giving fewer but larger radiotherapy doses at each visit, over a shorter period of time. This will allow patients to complete radiotherapy within 2 weeks rather than within 4 or 7-8 weeks. We can achieve this by using advanced, more accurate radiotherapy technology (stereotactic body radiotherapy, SBRT).

SBRT allows doctors to better focus the radiation on the tumour. This reduces the chance of damaging surrounding healthy tissue. This damage can cause side effects such as more frequent or urgent urination and diarrhoea.

#### ***Background***

Patients joined the trial and had radiotherapy treatment between August 2012 and March 2018. The trial was carried out in 37 hospitals in the UK, Ireland and Canada.

The PACE-B participants were allocated at random to one of the following radiotherapy treatment groups:

- 1) **Group 1 - Standard radiotherapy** - either 78 Gy\* in 39 fractions\*\* over 7-8 weeks, or 62 Gy\* in 20 fractions\*\* over 4 weeks (depending on what the standard treatment was at each hospital taking part).
- 2) **Group 2 - SBRT** - 36.25 Gy\* in 5 fractions\*\* over 1-2 weeks).

*\*grays (Gy) are the units, or amount, of radiotherapy given*

*\*\* Fractions are daily radiotherapy treatments*

Roughly half of the men in PACE-B trial had their radiotherapy over 4-8 weeks (“standard radiotherapy”) and half received their radiotherapy in 5 days (“SBRT”). No participants received hormone therapy.

---

<sup>1</sup> The full results have been presented at a large scientific/medical conference and the scientific summary of what was presented can be seen here: LBA 03, page e2  
[https://www.astro.org/ASTRO/media/ASTRO/Meetings%20and%20Education/PDFs/AM23/2023\\_LBAs\\_corrected.pdf](https://www.astro.org/ASTRO/media/ASTRO/Meetings%20and%20Education/PDFs/AM23/2023_LBAs_corrected.pdf)



874 men with low to medium risk prostate cancer were randomly assigned treatment.



Standard radiotherapy given over 20 or 39 visits.



SBRT, radiotherapy given in over 5 visits.



We have previously looked at any side effects that patients experienced and how bad they were in both the short (up to 12 weeks after treatment) and longer term (up to two years after treatment). We have now been monitoring everyone in the trial for five years or more, so we can also look at how well the treatments have worked to prevent participants' prostate cancer from returning.

### ***How well do the treatments work?***

We looked at both treatment groups to see if there is any difference in the number of participants whose cancer has come back by five years after treatment.

We found that both groups had high rates of cancer control, much better than we had expected, and the rates were similar in both groups. Over 95 out of 100 men in both groups were free of cancer at five years.

### ***Side effects of treatment***

We have previously looked at how participants were feeling up to two years after radiotherapy treatment. We found that, on average, men who received SBRT had slightly more bladder side effects and slightly fewer bowel side effects than men receiving longer radiotherapy. Although overall, the number of people having any side effects was much smaller than we expected, and no-one had any really serious side effects.

We looked at the side effect data again as part of this analysis and we found that five years after treatment very few men have any ongoing bladder or bowel side effects and there is no difference between the two groups at this time.

### ***Summary***

The SBRT treatment is just as good at preventing prostate cancer from returning, and as safe, as the radiotherapy that would usually be given. We can be confident that people can have SBRT treatment, with fewer visits to the hospital for radiotherapy, without it changing how well their cancer is treated. The high rates of cancer control in both groups were achieved without the use of hormone therapy.

We recommend that this new SBRT treatment should be made available to everyone with this type of prostate cancer and that it should become standard of care.

***What will happen now?***

The results of the trial have been presented at an international conference called ASTRO. These results will then be published in a scientific journal.

Without the contribution of the patients that took part in this study, research like this would not be possible. We would like to thank them all for their ongoing support.

The PACE-B trial was funded by Accuray, sponsored by The Royal Marsden Hospital, coordinated by the Clinical Trials and Statistics Unit at The Institute of Cancer Research (ICR-CTSU) and endorsed by Cancer Research UK. The Chief Investigator is Prof Nick van As.