

The PACE Trial

Results of the short term side effects of prostate cancer treatment in PACE-B: conventional radiotherapy vs stereotactic radiotherapy

Previously you kindly agreed to take part in a research study called PACE-B. We have now looked at side effect data collected from all the study participants 3 months after completing radiotherapy and we would like to share the key results¹ with you.

What is the study about?

The aim of the PACE-B study is to see whether we can improve radiotherapy treatment for men with prostate cancer by seeing if we can give fewer but larger radiotherapy doses at each visit, over a shorter period of time, so that radiotherapy is completed within 2 weeks rather than within 4 or 7-8 weeks. We want to achieve this by using advanced, more accurate radiotherapy technology (stereotactic body radiotherapy, SBRT).

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

Background

You were one of the 847 men with prostate cancer who joined the trial between August 2012 and January 2018. The trial was carried out in 40 hospitals in the UK, Ireland and Canada.

When you consented to take part in PACE-B you 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 at your hospital was when you entered the trial).
- 2) **Group 2 - SBRT** - 36.25 Gy* in 5 fractions** over 1-2 weeks).

**Gray (Gy) is the units or amount of radiotherapy given*

*** Fractions are the daily radiotherapy treatments*

1 The full results were published in a medical journal in September 2019 so that doctors around the world can be made aware of the findings. You cannot be identified personally from any of the data used in any of the presentations or publications. The publication is called "Intensity-modulated fractionated radiotherapy versus stereotactic body radiotherapy for prostate cancer (PACE-B): acute toxicity findings from an international, randomised, open-label, phase 3, non-inferiority trial" and is available at the following web address if you are interested: [https://doi.org/10.1016/S1470-2045\(19\)30569-8](https://doi.org/10.1016/S1470-2045(19)30569-8).

Any side effects that you experienced and how bad they were was assessed during and after your treatment, both by the cancer doctors at your hospital and by completing quality of life questionnaires. Our researchers have looked at assessments from the doctors and the questionnaires you completed.

What did the data show?

The side effect data collected over the first three months after treatment, show that patients who had SBRT had similar and low levels of side effects when compared to the patients who had conventional, standard of care, radiotherapy. The overall number of patients and doctors reporting side effects 3 months after treatment in both groups was smaller than expected.

At 3 months, moderate or severe gastrointestinal side effects (such as, diarrhoea, discomfort in the back passage, or changes in bowel habit) as assessed by a cancer doctor, were reported by:

about **12 out of 100** (12%) patients having standard radiotherapy (**Group 1**)

about **10 out of 100** (10%) patients having SBRT (**Group 2**).

At 3 months, moderate or severe genitourinary side effects (such as, needing to pass water more frequently, problems passing water or bladder incontinence) as assessed by a cancer doctor, were reported by:

about **27 out of 100** (27%) patients having standard radiotherapy (**Group 1**)

about **23 out of 100** (23%) patients having SBRT (**Group 2**).

Patient reported side effects measured in the questionnaire were found to be very similar between the two treatment groups.

What do our researchers say?

The doctor leading the study, Dr Nicholas van As, Consultant Clinical Oncologist at The Royal Marsden NHS Foundation Trust, said:

“It is reassuring to see from this trial that SBRT does not significantly impact patients’ quality of life in the short term, compared with the current standard of care. Using SBRT to deliver this treatment would mean that patients could be spared numerous visits to hospital, allowing them to get back to their lives sooner.”

“These results are promising, and for the first time show in a large patient group that giving five large doses of SBRT is safe in the short term. It is important to point out that we will not know for another few years about the long term side effects and outcomes of treatment, and that this treatment technique is still only available in a trial setting in the UK”.

What will happen now?

We will continue to collect data over the next few years. Results comparing how well each treatment worked in controlling the cancer will not be available for a while. A separate information sheet will be made available when these results are known.

Thank you for taking part in PACE-B and for completing questionnaires. We would like to remind you of the importance of attending your clinic appointments; we would like to continue to follow you in the study for at least 10 years. Without the contribution of people like you, this study would not be possible. If you have any questions about these early side effect results from PACE-B, please discuss this information sheet with your local cancer doctor or a member of their team who will be happy to help you.

Local Consultants name:

Address:

Telephone:
