

# ProtecT Study

(Prostate testing for cancer and Treatment)

## Newsletter Issue 16, 2023

### ProtecT study fifteen-year results published

New long-term ProtecT study results were published recently (see below\*). This newsletter contains a summary of the main findings. These results are about the men who agreed to be randomised to active monitoring or surgery or radiotherapy. These three groups were compared up to the end of 2020 - over an average of 15 years.

The main findings are:

- There was very high survival and very few deaths from prostate cancer.  
3 in 100 men died of prostate cancer – meaning 97 out of 100 men in the ProtecT study survived prostate cancer for an average of 15 years after diagnosis.
- There were no differences in survival between the active monitoring, radiotherapy, and surgery groups.  
The same high survival rate with prostate cancer was found in all three groups.
- Cancer progression and spread were different between the groups.  
Cancer progression is when cancer grows beyond the edge of the prostate. Cancer spread (also known as metastases) is when cancer cells spread to other parts of the body, such as bones.  
Cancer progression and spread occurred in more men in the active monitoring group compared with the surgery and radiotherapy groups. The numbers are important:
  - 5 in 100 men in the surgery or radiotherapy groups had cancer spread (metastasis) compared with 9 out of 100 men in the active monitoring group. This means that 95 out of 100 men in the radiotherapy or surgery groups (95%) did not have evidence of cancer spread compared with 91 out of 100 in the active monitoring group (91%).
  - Many men who had developed metastases (cancer spread) by 2015 in the active monitoring group were alive at the 2020 follow-up (19 out of the 22 with metastases in 2015 – 86%).
- Treatment side-effects were different between the groups.  
Side-effects of treatments were experienced by more men in the surgery and radiotherapy groups than in the active monitoring group. Some side-effects continued or worsened in the longer term.
  - More men in the surgery group reported leaking urine than in the active monitoring or radiotherapy groups. By the end of follow up, nearly 1 in 4 men (25 in 100) in the surgery group reported needing to wear pads to protect against urinary leaking, compared with 8 in 100 in the radiotherapy group, and 11 in 100 in the active monitoring group.
  - Sexual function declined in all groups over time. However, men in the surgery group experienced the greatest impact on their sex life, with the radiotherapy group experiencing some but less impact, and the active monitoring group the least impact. At seven years, around 30 in 100 men in the active monitoring group or radiotherapy group could achieve an erection firm enough for intercourse compared with 18 in 100 in the surgery group.

- Leakage of faeces once a week or more was higher in the radiotherapy group than the other groups. By 12 years, this affected 12 in 100 men in the radiotherapy group compared with 6 in 100 in the surgery or active monitoring groups.
- In the active monitoring group, 1 in 4 men (25 in 100) did not receive any treatment for prostate cancer and were alive and well after an average of 15 years. Men who stayed on active monitoring avoided the side-effects of surgery and radiotherapy treatments. However, 61 in every 100 men the active monitoring group had received surgery or radiotherapy by the end of follow-up.

## Conclusions

The ProtecT findings are very good news for men diagnosed with localised prostate cancer after PSA (Prostate Specific Antigen) testing. The vast majority of these men live a long time, whatever treatment they have. Each treatment has a different pattern of side-effects and impact on cancer progression and spread. The information you provided to the study nurses and in the questionnaires you filled in so faithfully has produced these results. Your contribution has been extremely valuable. This clear and helpful information will enable other men with localised prostate cancer and their doctors to carefully assess the pros and cons of each treatment. Men can use their own values and priorities to make well-informed treatment decisions with their doctor and family. In addition, with the understanding now that they will live a long time whichever treatment they choose, they do not need to rush to decide. They can take their time and make the decision that is best for them.

## Thank you!

We are extremely grateful for your participation in the ProtecT study. The information you provided has improved the treatment of men with localised prostate cancer in the UK and around the world. The first results of the study published in 2016 were included in the UK NICE (National Institute for Health and Clinical Excellence) guidelines that all UK clinicians use to guide their practice. We expect these new findings will also be included in the next revision of these guidelines. Other countries have also used the ProtecT study findings in their guidelines – including across Europe, USA, Australia, and Canada, and other countries around the globe. The information you have provided will continue to improve treatment for men with prostate cancer in the future.

### \*Recently published papers:

Hamdy FC, Donovan JL, Lane JA, et al. ProtecT Study Group. Fifteen-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Prostate Cancer. *N England Journal of Medicine*. 2023; 388 (17).  
<https://www.nejm.org/doi/10.1056/NEJMoa2214122>

Donovan JL, Hamdy FC, Lane JL, et al. ProtecT Study Group. Patient-Reported Outcomes 12 Years after Localized Prostate Cancer Treatment. *NEJM Evidence*. 2023; 2 (4).  
<https://evidence.nejm.org/stoken/default+domain/JCWRDZJ8CKRNGH6A6ZZF/full?redirectUri=/doi/full/10.1056/EVIDoa2300018>

### Other reports on the study:

<https://blogs.kcl.ac.uk/cancerprevention/2023/03/31/findings-from-the-protect-trial-a-good-news-story/>

<https://www.nejm.org/doi/10.1056/NEJMdo007017/full/>

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-treatment-approaches-for-prostate-cancer>