

ProtecT Study

(Prostate testing for cancer and Treatment)

Newsletter Issue 14, Autumn 2016

ProtecT trial – first main outcome results published

The first main ProtecT study results were published on September 14th (for details see below*). As we explained in the last ProtecT study newsletter, you may already have seen or heard reports in the newspapers, TV, radio or on-line. This newsletter contains a summary of the main findings. These first results present the outcomes of the men who agreed to be randomised to the active monitoring group or surgery group or radiotherapy group. The groups are compared up to the end of 2015 - over an average of 10 years.

The headline findings are:

- There were very few deaths in the active monitoring, radiotherapy and surgery groups

1 man in 100 died of prostate cancer – meaning that 99% of men in the ProtecT trial survive with a diagnosis of prostate cancer

The same 99% survival rate was found in the active monitoring, radiotherapy and surgery groups

1 man in 10 died from causes such as heart disease, stroke or other cancers – meaning that 90% of men in the ProtecT trial are alive

- Cancer progression and spread were different between the groups

Cancer progression is when the cancer grows beyond the edge of the prostate. Cancer spread (also known as metastases) is when the cancer cells spread to other parts of the body, such as the bones.

Cancer progression and spread happened in twice as many men in the active monitoring group compared with the surgery and radiotherapy groups. The numbers are important:

- 9 out of 10 men in the radiotherapy or surgery groups (90%) did not have evidence of progression compared with 8 out of 10 in the active monitoring group (80%).
- 97 to 98 out of 100 men in the radiotherapy or surgery groups (97-98%) did not have evidence of cancer spread compared with 94 out of 100 in the active monitoring group (94%).

- Treatment side-effects were bothersome and different between the groups

General quality of life issues in terms of physical mobility and mental wellbeing were the same between the groups, but bothersome treatment side-effects were different.

Urine leakage (incontinence) and sexual difficulties were more common in the surgery group than in the other groups. There was some improvement after the first six months, but more men continued to be affected by these problems in the surgery group than the other groups throughout follow up.

Bowel problems, sexual difficulties and some problems with urination were experienced more often in the radiotherapy group at six months. Most of these problems got better in most men over the next two years, but some men experienced increasing blood in stools over time.

Men who stayed on active monitoring avoided the side-effects of radical treatments. However, half of the active monitoring group changed to surgery or radiotherapy by the end of follow-up. Some urinary and sexual difficulties increased gradually over time after these treatments or because of natural declines from getting older. We are now looking in detail at the reasons why men changed to other treatments. So far we know that these reasons included possible signs of cancer progression, advice from the treating consultant, and patient choice.

Conclusions

Active monitoring, radiotherapy and surgery all have important roles in treating prostate cancer.

With **active monitoring**, there is very good survival, but there is an increased risk of cancer spread and progression for some men. There is the opportunity to avoid the troublesome side effects of surgery and radiotherapy, but half the men changed to these treatments by the end of follow up.

With **radiotherapy**, there is the same very good survival and a reduction in the risk of cancer spread and progression (compared with active monitoring), but there are bothersome impacts on sexual, bowel and urinary function particularly at six months. These problems mostly resolve over the next two to three years.

With **surgery**, there is very good survival and a reduction in the risk of cancer spread and progression (compared with active monitoring), but there are bothersome impacts of urine leakage and sexual difficulties for many in the first six months. There is then some recovery over the following two to three years, but some urinary leakage and sexual difficulties continue for some men for six years.

More research is needed to identify the cancers that will progress or spread, and those that do not.

Longer follow up is needed to find out how survival, progression and spread of cancer, and quality of life will change over the next five to 10 years.

What do these results mean for you?

These first results will help us to shape your future follow up by your ProtecT study consultant and the research team. If you have any concerns about the results or wish to discuss things further, please contact your local ProtecT study consultant (listed overleaf).

The ProtecT trial, funded by the National Institute for Health Research (NIHR) is the largest study of its kind in the world. The data you have provided means that active monitoring, radiotherapy and surgery have now been directly compared for men with PSA-detected localised prostate cancer. These results will improve treatment for men in the future.

We are extremely grateful for your participation in the ProtecT study so far. These results are the first main results – many more will follow. It is also really important that we continue to follow you up within the study. NIHR have let us know that they will continue to fund the study for the next five years at least. We are now working hard to prepare shorter follow up questionnaires and research data to be collected by the ProtecT study nurses at your annual research visits. We very much hope that you will continue to take part so that we can all find out what happens next and complete the picture.

Further details and contacts

*The published papers are:

* Hamdy FC et al Mortality and clinical outcomes at 10-year follow up in the ProtecT trial. New England Journal of Medicine, September 14th 2016. <http://www.nejm.org/doi/full/10.1056/NEJMoa1606220>

* Donovan JL et al Patient-reported outcomes over 6 years in the ProtecT prostate cancer trial. New England Journal of Medicine, September 14th 2016 <http://www.nejm.org/doi/full/10.1056/NEJMoa1606221>

We will be sending more details about ProtecT study results in future newsletters, as well as the regular features and stories. Research has shown that some participants would prefer not to receive information about study results. If you do not wish to receive more information about ProtecT study results please let us know this on Freephone 0800 7833167, email: info-protect@bristol.ac.uk, or write to: The ProtecT Study, University of Bristol, Canynge Hall, 39 Whatley Road, Bristol, BS8 2PS. If you have any comments about the newsletter please also contact us.

You will be able to discuss the study results with the ProtecT study nurse at your next research follow up visit. If you have particular concerns, please contact the consultant named below at the clinical centre, who will be happy to help.

ProtecT Consultants at clinical centres for clinical care

Birmingham	Mr Alan Doherty: 0121 6978273
Bristol	Mr Edward Rowe: 0117 4140944
Cambridge	Mr Vincent Gnanapragasam: 01223 331940
Cardiff	Professor Howard Kynaston: 02920 748165
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ProtecT study nurses for research follow up visits

Birmingham	Pauline Thompson: 07584 461471
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