

ProtecT Study

(Prostate testing for cancer and Treatment)

Newsletter Issue 9, Winter 2011

Welcome to the 9th annual ProtecT study newsletter.

First of all we would like to thank all of you for your continued support. Whether it's completing questionnaires, attending our centres or speaking to research staff, all your contributions are vital to the success of ProtecT.

As another year of follow-up draws to a close, the ProtecT study is still on course to greatly improve our understanding of the long term effects of the treatments for prostate cancer. The continued good progress was confirmed by Professor Michael Baum, independent chairman of the ProtecT Trial Steering Committee which met in January of this year (front row, second from right, see photo.)

In this newsletter we highlight some of the new research linked to the ProtecT study as well as the results of other prostate cancer trials worldwide.

This year there are also some accounts from ProtecT study participants which we hope you will find interesting.



The ProtecT Trial Steering Committee in London 2011

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Protect Study in Follow-up

109,000 men entered the Protect study or enough to fill the Michigan Stadium in the US.



Picture courtesy of Andrew Horne

Approximately 2500 men were found to have localised prostate cancer (enough to fill this cruise ship)



The average age of men in the study is now 65, the same age as the actor Alan Rickman.

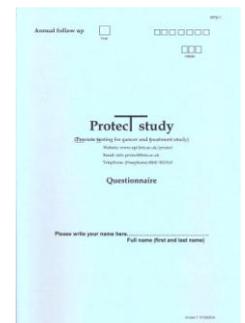


Picture courtesy of Joella Marano

Some men have been taking part in the study for 12 years. In fact, they joined in the same year as the Euro was introduced.



We still would like you to complete the annual questionnaires and visits.



Presentations

During the last 12 months, Protect researchers have given presentations at a number of national and international conferences. Protect principal investigator, Professor Jenny Donovan, has given a presentation about the active monitoring treatment at an international research conference in Washington in December 2011 funded by the US government. In January Dr Athene Lane, Study Coordinator, will give a research talk on active monitoring in Rotterdam at a European meeting of clinicians.

Study Publications

In the last year, Protect study data, largely provided by yourselves, was used for over 20 papers which have appeared in a number of prestigious academic journals.

Whilst the language used to write these papers can sometimes be complex, here are two that you may find of interest:

Association of obesity with prostate cancer: a case-control study within the population-based PSA testing phase of the Protect study (British Journal of Cancer 2011, 104: 875-881. Dimitropoulou, P. et al)

<http://www.nature.com/bjc/journal/v104/n5/full/6606066a.html>

Seasonal variation in prostate specific antigen levels: a large cross-sectional study of men in the UK (British Journal of Urology International 2011 Mar 31. doi: 10.1111/j.1464-410X.2011.10174.x. Down, L. et al)

<http://onlinelibrary.wiley.com/doi/10.1111/j.1464-410X.2011.10174.x/full>

These 20 papers published include genetics, epidemiology and men's experience of biopsy.

Protect Staff News

Andrea Wilson retires

Andrea Wilson, lead administrator for the Protect study, retired this year after 12 years involvement with the Protect study. Based at the University of Bristol, Andrea started working on Protect when it began in 1999 and saw it expand from a pilot study in three centres to the nationwide study it is today. As head of the administrative team based at Bristol University's School of Social and Community Medicine, Andrea was responsible for keeping the engine rooms of Protect working.



Andrea being presented with a bottle of wine at her retirement party.

She is held in the highest esteem by all those who had the pleasure of working with her, both at Bristol University and the nine clinical centres.

Professor Jenny Donovan, Principal Investigator for the Protect study, paid the following tribute: "Andrea's was the first appointment to the study, and she did absolutely everything on the admin side and more. The study would not have got off the ground without her hard work in those early days."

Andrea now spends her time travelling around the West Country in her camper van and looking after her granddaughters, Brooke and Freya.

More staff news

Protect data managers, Michael Davis and Liz Down, have both become the proud parents of baby girls this year; Greta and Rose respectively. Eleanor Walsh, who has been providing maternity cover, has stayed on since Liz returned in November.

Pippa Herbert, lead nurse at the Cambridge centre, also had cause to celebrate this year after she gave birth to a baby boy. Noah Quinn Herbert was born on the 6th October 2011 and will compete for attention in the Herbert Household with his sister, Phoebe.

HeLPP (Healthy Living in Protect Participants) study update by Eleanor Walsh, Research Assistant / University of Bristol

The Protect study participants have provided questionnaires, blood samples and DNA which has been used by researchers investigating prostate cancer causes, treatments and disease progression. Valuable insights have already emerged from this data and we would now like to make it available to researchers investigating other health issues and diseases, e.g. heart disease. We need your permission before any additional research can commence.

The HeLPP study has contacted over 25,000 men to ask their permission for the data already provided to the Protect study to be used in research into other diseases.

By agreeing to take part in the HeLPP study, researchers interested in health issues other than prostate cancer will be able to use the information you have already provided Protect for a wide range of studies.

Look out for your information pack describing what is involved in more detail coming soon!

For further information email: info-protect@bristol.ac.uk

The effects of prostate biopsy (ProBE study)

Mr Derek Rosario & Ms Louise Goodwin
(Sheffield University & Royal Hallamshire Hospital)

Why carry out this study ?

Up to now there has been limited information about the risks and perceptions of prostate biopsy..... and you may wonder why this is, considering that prostate biopsy has been an investigation that has been carried out on thousands of men for many years.

Most previous studies were based on the experiences of patients referred to a Urologist for suspected prostate problems, prior to undergoing a prostate biopsy. Most studies also concentrated on the 'medical' definitions and perceptions of side effects, rather than on how things were for the men themselves. The more recent use of patient-reported outcome measures (PROMS) in questionnaires is more helpful in understanding the impact of side-effects.

Recruitment

Between February 2006 and May 2008, 1147 of men, aged between 50 and 69 years old, as part of the ProtecT study, also agreed to be followed up for 35 days after undergoing prostate biopsy for the first time (ProBE study.)

Using a structured questionnaire as well as telephone follow-up, we asked men how the prostate biopsy experience had been, both immediately and up to 35 days afterwards. This study had an excellent response rate with more than 1000 men returning their questionnaires

Results

Immediate effects:

- 3% (3 in a hundred) felt 'light-headed' or experienced dizziness after the biopsy.
- 15% (1 in 6 men) experienced moderate or severe pain caused by the biopsy.
- 7% (just under 1 in 10) passed blood in their urine immediately afterwards and 3% passed clots in their urine at this time.

Delayed effects (during the 35 days after the biopsy):

- 44% (1 in 2) had a degree of discomfort or pain and 7% found this to be a moderate or severe problem.
- 20% (1 in 5) felt feverish and 5% found this to be a moderate or severe problem.



Mr Derek Rosario

- 66% (two thirds) had blood in their urine but only 6% reported this as a moderate or severe problem.
- 37% (1 in 3) had blood in their motions, but only 2% reported this as a moderate or severe problem.
- 90% (9 in 10) had blood in their semen and 25% found this to be a significant problem.

Feeling unwell in the 35 days after biopsy:

- 1 in 10 men felt unwell enough to visit his GP
- 1 in 100 men required admission to hospital

Conclusions

The relatively low rate of serious infection was quite reassuring. Of particular concern to men was the frequent rate of blood in the semen, which men seemed unprepared for and caused considerable concern. These side-effects may influence men's attitudes towards possible further biopsy in the future and also on community care services.

The future

The results are being published in the British Medical Journal. It is hoped that the results of this study will be of use to men when they are considering undergoing investigations for prostate cancer detection. It will also assist doctors in informing their patients about potential risks and impact of biopsy when they are discussing the events that may follow on from a PSA blood test if it is raised. Awareness of these results in Urology Departments around the country will encourage ever improving standards of care before, during and after prostate biopsy.

The research team would like to say a big thank you to everyone involved in ProBE. This study could not have been done without you!

New prostate cancer results

Advances in the treatment of late stage prostate cancer

A global study has shown that the use of radium-223 chloride to target bone metastasis in men with late stage prostate cancer can significantly improve life expectancy. The ALSYMPCA trial, which recruited 922 men, was halted early when researchers discovered that those who were given radium-223 chloride were living on average nearly three months longer. As Dr Chris Parker, the trial leader at the Royal Marsden Hospital in London said: "It would have been unethical not to offer the active treatment to those taking placebo."

Whilst there are drugs available now which help to alleviate the symptoms of bone disease caused by prostate cancer the new drug, Alpharadin, is the first to improve survival. The treatment is not licensed for use in the UK yet but researchers are confident that it may become standard practice in the future. It is also hoped that future clinical trials will prove the effectiveness of radium-223 chloride in treating other types of cancer which have metastasised to bone.

The PIVOT study

The Prostate Cancer Intervention Versus Observation Trial (PIVOT), a US based research project unveiled its initial findings in May. The trial, which began in 1994, was designed to measure the effectiveness of surgery compared to observation in relation to overall life expectancy and cancer-specific mortality on men with localised prostate cancer.

Researchers encountered difficulties when persuading the 5,000 patients who were assessed and deemed eligible for the study to be randomised. In the end, 731 agreed to be randomised with 364 selected to have surgery and 367 observation.

Dr Timothy Wilt, who presented the study's initial findings at the 2011 annual meeting of the American Urological Association (AUA), stated that:

"Surgery did not reduce mortality more than observation in men with low PSA or low risk from prostate cancer.....[but the trial results].....suggest a benefit from surgery in men with higher PSA or higher risk disease."

In conclusion, Dr Wilt observed that, compared to observation, surgery offered:

"reductions in all-cause and prostate cancer mortality that were not significant and less than 3% in absolute terms over 12 years."

More information about prostate cancer

If you would like to read more about prostate cancer, the ProtectT study suggests the following websites are good places to start.



<http://www.prostate-cancer.org.uk>

The Prostate Cancer Charity provides one of the most comprehensive guides to prostate cancer available on the net. The publications section has a number of booklets which can be downloaded or ordered by post. There is an online community of over 4000 men who help and support each other by sharing their experiences. Registration is free and only takes a few minutes. There is also a research section which provides general information about how clinical trials works. You can call their helpline on 0800 0748383.



<http://www.prostate-link.org.uk>

The UK Prostate Link acts as a comparison website for information relating to prostate cancer. It claims to assess the quality of information found on over 50 other websites to provide the most reliable information about prostate cancer for its visitors.



<http://www.epi.bris.ac.uk/protect>

Please visit the ProtectT study's very own website for specific information relating to the study you are taking part in. You can view the latest contact details of study personnel and browse previous issues of the newsletter.

Men taking part in the ProtecT study

Malcolm Davidson from the Leeds centre

His doctors didn't think he could do it but Malcolm Davidson, 70, proved them wrong on the 25th September 2011 by cycling the 140km Stoke-On-Trent Pro Ride. In addition to being diagnosed with prostate cancer in 2007, Malcolm was found to have Mesothelioma (a type of lung cancer caused by asbestos exposure) in January of this year. Because his treatment for lung cancer only finished on the 9th May 2011, it was perhaps understandable that the medical profession was dubious when Malcolm stated his intention of returning to high level cycling.

The course Malcolm completed, which is an official stage of The Tour of Britain, has a total elevation of 1965m - or the equivalent of climbing Scafell Pike and Snowdon: the two biggest mountains in England and Wales. Not most people's idea of fun, it is Malcolm's enjoyment of uphill cycling which has helped him earn the nickname Mad Mal.

After the race, which raised funds for The Prostate Cancer Charity, Malcolm paid tribute to his two team mates from the Leeds cycle club, Seacroft Wheelers: "Fred Lyn and Andy Shearman did a great job pacing me round, I also did my share on the flat, on the steep climbs I suffered badly but got up them all with their encouragement."



Malcolm feels that cycling gives him a boost and helped him to cope with his recent health problems.

Mike Hocking from the Cardiff centre



Mike describes the trek as unforgettable. The first two days took him through rainforest where he saw Colobus and Blue Monkeys, elephant footprints and evidence of buffalo. He then made his way through heath land and eventually a desolate rocky landscape. The final day began at midnight and involved walking for a gruelling 14 and a half hours. They reached the summit at 8.40am and the views from there were absolutely breathtaking.

In 2012 Mike plans to keep running whilst also spending time with his five year old granddaughter, Kenzi. Mike keeps in regular contact with the ProtecT team in Cardiff.

Despite having no symptoms, Mike Hocking was diagnosed with prostate cancer just 6 months after his 50th birthday. Mike considers himself lucky to have been diagnosed early and has vowed to raise as much money as he can for prostate cancer research.

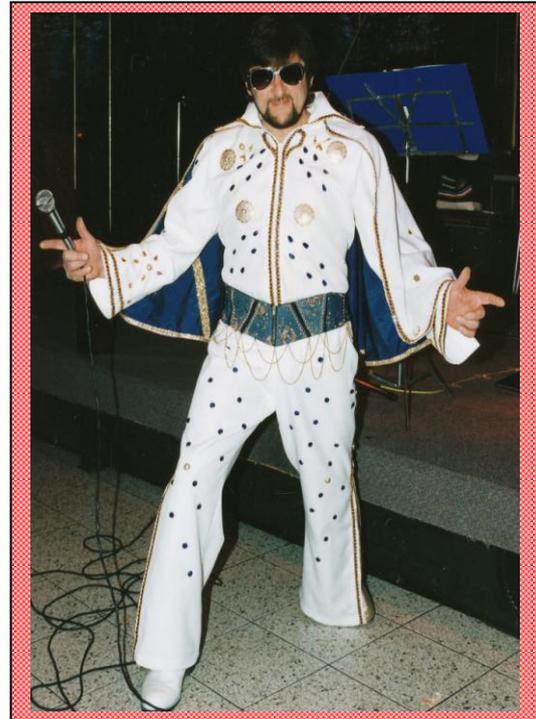
In 2009 he ran the Edinburgh Marathon; raising £1,170. The following year Mike was sent some information that included the details of a Kilimanjaro trek and immediately the prospect of adventure fired his imagination.

Standing at 19,341ft, Kilimanjaro is the highest mountain in Africa and the biggest free standing mountain anywhere in the world. Mike paid for the trip himself so that all the money he raised would go to charity.

Gerald White from the Bristol centre

Gerald White leads a double life as an Elvis Impersonator. The first time Gerald took to the stage he was 42 years old. He still remembers that night back in 1993 when he played to a packed house at the Bell on Two Mile Hill Road in Bristol. It was a long evening for Gerald but his nerves held out and he has never looked back.

Twenty years and over 1000 gigs later, Gerald has performed at some of the top music venues around the world. He's sung at the Colston Hall with veteran rockers the Bristol Comets. He's been to Nashville and sang at the legendary Grand Ole Opry whose stage has been graced by the likes of Hank Williams and Elvis Presley himself back in 1954.



Gerald joined the ProtecT study in 2008. He has performed for the ProtecT nurses at Southmead Hospital in Bristol and hopes he didn't offend them when he sang 'In The Ghetto.' Lately he has branched out; invested in a black suit and cowboy hat and also performs Johnny Cash songs too.

Jim Anderson from the Edinburgh centre

"It was an amazing feeling," said Jim Anderson as he recalled the moment when two Oceanic White Tipped Sharks swam by whilst he was scuba diving in the Red Sea. Whilst most people would have panicked, Jim calmly reached for his underwater camera and began taking photographs (see right).

Jim Anderson's passion for scuba diving began in 1987 when on a family holiday in the Seychelles. It was something he had always wanted to try so on his return to his native Scotland he joined a local sub-aqua club.

One of the first questions Jim asked the doctors when he was diagnosed with prostate cancer in 2003, was whether he would be able to carry on diving.

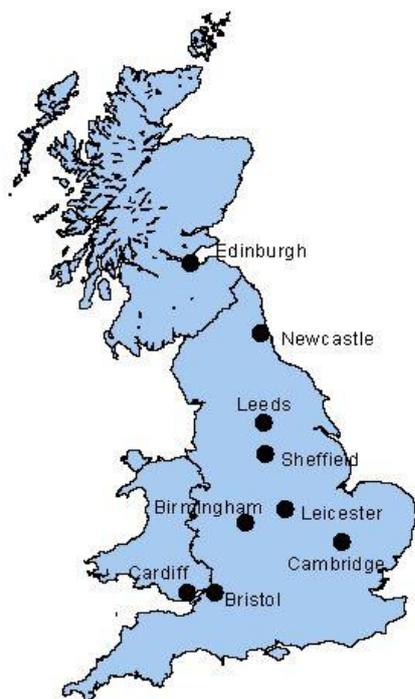
They saw no reason why not and, sure enough, Jim was soon back in the water.

Jim has never looked back and continues to travel worldwide in search of new underwater experiences.

Jim admits that he was 'shattered' when first diagnosed with prostate cancer, but he now views his involvement with ProtecT in a positive light.



Useful Information



You can contact the **lead research nurse** at your local centre.

Birmingham: Pauline Thompson (0121 6272992)

Bristol: Lynne Bradshaw and Tricia O'Sullivan (0117 3235080)

Cambridge: Phillipa Herbert (01223 596225)

Cardiff: Sarah Tidball (02920 746501)

Edinburgh: Norma Lyons (0131 5372433)

Leeds: Debbie Cooper (0113 2063509)

Leicester: Sue Bonnington (0116 2588316)

Newcastle: Teresa Lennon (0191 2231461)

Sheffield: Joanne Howson (0114 2712791)

What if I move?

We would very much appreciate you letting us know your new address, contact telephone number and e-mail if you have one.

How to contact us:

- Inform a ProtecT research nurse at your local centre
- Email us at: info-protect@bristol.ac.uk
- Telephone Freephone 0800 7833167
- Write to us at: The ProtecT Study, University of Bristol, Canynge Hall, 39 Whatley Road, Bristol, BS8 2PS.

Our Birmingham office has moved:

Room 19,
Clinical Research Offices, Old Nuclear Medicine Department,
1st Floor Pharmacy Building
Research & Education
University Hospital Birmingham
NHS Foundation Trust,
Queen Elizabeth Hospital
Queen Elizabeth Medical Centre
Birmingham
B15 2TH
The telephone number is the same.

Who funds the ProtecT study?

The NIHR Health Technology Assessment (HTA) Programme is funded by the Department of Health (www.doh.gov.uk). The HTA website is www.hta.ac.uk - Postal address: NETSCC, HTA, Alpha House, University of Southampton Science Park, Southampton, SO16 7NS, Tel: 023 8059 5586, Fax: 023 8059 5639, Email: hta@hta.ac.uk

Keeping you informed

We hope you have enjoyed this newsletter. If you have any ideas about the next issue the study coordinator, Dr Athene Lane, would be very happy to hear from you via email or telephone above.

Finally, another big thank you for all your help and support over the last year.