

Prostate Matters

Newsletter

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It is intended to publish this newsletter 4 times a year
Winter - Spring

Summer - Autumn

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Charity No. 1123373

Worried or concerned about prostate cancer?

National Help Line
0845 601 0766

Comment on Prostate Cancer Research

The need for research into the causes, characterisation and treatment of prostate cancer is widely accepted. How can the Federation make an impact on this research? Currently the Federation is a stakeholder in NICE and has representation on: PCCA, EUROPA UOMO, several consumer liaison groups and on clinical trial committees.

During 2008 the Federation committee was able to make contributions to the NICE review and, more importantly, to the Prostate Cancer Risk Management Programme (PCRMP). However little attention was paid to our comments, and we received no direct replies to our concerns (see report on page 3).

Periodically, our opinions will be sought on aspects of research or treatment but, in order to make these more representative of the total membership and to make more impact, we need to garner opinion across the Federation. To some extent we can poll views at meetings, but perhaps the simplest way to do this is ask local committees, within the Federation, to provide views which can be coordinated by the Federation Committee.

Both the PCRMP documents concern the PSA test, and for many years this has been debated. According to Hans Lilja, it has now become a "religious argument", and sometimes this does seem to be the case, especially in regard to population screening. Several trials have reported reduced mortality in screened populations, but these trials do not fit the requirements of fully randomised, highly-powered trials which can provide "evidence-based results". Similarly results based on epidemiology, comparing the decrease in mortality between the USA and UK over the same period (S.M. Collin et al. 2008) cannot be unambiguously assigned to PSA testing; although mathematical modelling supports this view (R. Etzioni et al. 2008).

Because of these uncertainties, the medical community focuses on two ongoing clinical trials: - the Prostate, Lung, Colorectal and Ovarian (PLCO) trial and the European Randomised Study for Prostate Cancer (ERSPC). Up to date these trials have provided data at yearly points over four years and conclude that "determining the effect of PSA screening on mortality awaits further follow up".

Commenting on the four-year update of the PLCO trial (BJUI Dec. 08) F. Schroeder (ERSPC) suggests that, on completion of these trials, "a meta-analysis might increase their power in showing differences in outcome and might also help to resolve some of the issues on how to best screen for prostate cancer in case the ongoing studies are positive". However in the meantime we are all aware of research over several years which has resulted in the recognition of several markers. These include measurement of fixed / free PSA, a test first reported by W.J. Catalona in 1988 (the PCRMP calls this a "new test"). Many biomarkers have been reported and developed since then. A recent review (ML Ramirez et al. 2008) considers 14 biomarkers and concludes that "few markers have been validated adequately and even fewer have been implicated in clinical practice. To date inconsistent and insufficient data suggest that no single marker is likely to achieve the desired level of sensitivity and specificity. More likely a combination of markers or serum profile will improve diagnostic accuracy of prostate cancer screening as well as the prognostic accuracy for influencing treatment". In view of the known complexity of prostate cancer this last sentence is, perhaps, not surprising. Consequently, an important theme for research concerns the need to evaluate (perhaps in collaboration with other countries) the efficacy of selected combinations of markers/serum profiles in achieving satisfactory prediction of diagnosis and prognosis. Additionally, it might help patients if some idea (target) of acceptable levels of such predictions could be agreed. In short, we would like to see more translational research.

John Dwyer, PCSF Chairman

Federation Holds Successful Workshop

Promoting Patient Power

Thanks to the generosity of the Graham Fulford Charitable Trust, a very successful workshop, entitled "Promoting Patient Power" was held in Leamington Spa on 16th October, 2008. It was attended by over 40 people, representing 21 member organisations.

The day was introduced by John Dwyer, Chairman of the Federation, and by our sponsor, Graham Fulford. They reviewed the history of the Federation and explained that the purpose of the workshop was to build on the very positive response to the Inaugural Conference last April.

The programme had two themes. One was to encourage discussion amongst delegates to progress ideas about what the Federation should seek to do, and how it should be organised and funded to achieve its aims. The other, in order to attract delegates, was a set of presentations on hot topics including PSA Testing and prostate cancer research priorities.

Way ahead workshop

Federation Secretary Sandy Tyndale-Biscoe opened the session and explained the process for the interactive workshop, in which delegates were divided up into groups and given 45 minutes to discuss any aspects of the Federation's structure, aims or modus operandi and then come up with a prioritised list of five key issues that should be taken forward by the Federation's Trustees.

At the plenary session following the various *rappoteurs* presented an unstructured list of the topics and issues. This can be broken down into the following broad areas:

Awareness, early detection and reduction in death-rate: raise awareness of prostate cancer with both the public and the profession; seek equality with breast cancer awareness; run a campaign – leaflets/information, books/posters; encourage early detection, education of GPs, promoting new tests, e.g. PCA3, and research leading to screening; influencing research directions for treatments; campaigning for access to new drugs; influencing patient pathways as developed by Cancer Networks and PCTs; monitoring implementation of the NICE Guideline.

PCSF public profile and recruitment: raise the presence/profile of the Federation; improve the website; maintain a register of supporting professionals; encourage collective power; run a major event in London/Parliament; advertise membership benefits; look for early success; find a high profile patron.

PCSF management: get the funding onto a firm footing – budget activities, identify funders; capturing new patients / increase membership; establish professional relationships with organisations.

Services to members: publicise information on available clinical trials; prepare handbook for forming groups; personal experience survey; buddy scheme; study and advise on impact on families.

The list above will be taken as a guide by the Federation Trustees in planning the future directions of the Federation.

Afternoon Session

After lunch delegates were treated to two presentations.

In the first, Mr David Baxter-Smith, Consultant Urologist from Kidderminster, gave a fascinating and informative presentation on how, supported by the Graham Fulford Charitable Trust, he has conducted a series of increasingly popular PSA Testing sessions throughout the country. He first explained why, despite the controversy over the test and its shortcomings, it is his firm belief that, used intelligently, the PSA Test is the only way to identify prostate cancer at a stage where it can reliably be expected to be cured. He went on to describe the process by which the sessions were set up. To ensure that

there is proper follow-up of results he writes to all men tested, giving the results and explaining what should happen next. Such letters are colour coded: green, amber and red. In the case of red letters, where a suspicious PSA level has been found, Mr Baxter-Smith recommends the man consults his GP urgently, but also gives his own contact details so that the man can discuss the implications of the findings.

In all, in these sessions, 6788 men have been tested, 426 red letters issued, and 152 cancers found and treated.

The presentation was very well received, and many delegates were interested in setting up their own testing sessions. During questions, Graham Fulford explained how these could be made self-financing.

The final session was entitled "Getting patients' voices heard in setting priorities for Prostate Cancer Research". Sandy Tyndale-Biscoe described how, after a request from the Prostate Cancer Research Foundation (PCRF) for patients to complete a research priorities questionnaire, very little response was achieved, primarily because the questionnaire was written with researchers in mind, and too detailed for a "consumer" to assess. He had prepared an alternative "Top Ten Questions in Prostate Cancer" questionnaire, which has produced good response, and a picture is beginning to emerge of what patients feel are the big issues. An exercise is now under way, with the PCRF, to get a consensus view on priorities for research.

The Workshop closed with thanks to Graham Fulford for generously

Federation Annual Conference & AGM

MOVING FORWARD

- RESEARCH

25th April 2009 - 10.30 to 4.30pm

Staffordshire University, Leek Road campus,
Leek Road, Stoke-on-Trent ST4 2DF

Full programme of speakers will be sent out to member groups
and published on our website when available

Prostate Cancer Risk Management Programme – men are betrayed again

by Sandy Tyndale-Biscoe

By the time you read this, the Department of Health (DH) will have sent out to all GPs a revised version of the Prostate Cancer Risk Management Programme (PCRMP), which is the Guidance to GPs on what to say to men with no symptoms who ask for a PSA Test. For men with undetected prostate cancer this is little short of a disaster. The guidance is very negative in tone, shows a strong bias against the PSA Test, and, above all, fails to take account of many very positive developments in clinical practice over the past five years.

The PCRMP was originally published by the DH in 2002 as an *apologia* for there being no plans to introduce a screening programme for prostate cancer, even though it kills more men than any other male cancer. It presented a one-sided, heavily opinion-loaded, negative view of the PSA Test and had the pernicious effect of influencing GPs to discourage men at risk of prostate cancer from having a PSA test. It has contributed to the steady stream of men first presenting with advanced, incurable disease, and therefore to the unacceptably high death rate.

After much lobbying and discussion in the Prostate Cancer Advisory Group (PCAG), about 2 years ago Prof. Mike Richards, the 'Cancer Tsar', agreed that the Guidance should be revised and the process opened up so that proper consultation on its content took place.

As one of four representatives of the Charter for Action, I was asked to join a Working Group officially charged with overseeing the revision process.

The initial meeting with the Revision Team (the same people responsible for the original document) was tense, but not un-promising. It was apparent that they were determined to respond to the accusation of bias, and in particular, we were promised that, where evidence is inconclusive, the negative tone generally adopted would be replaced with a more equivocal one, which would, where appropriate, include reference to current clinical practice. However,

this undertaking was never honoured. The "evidence based" principles of the authors were not to be compromised. Although many subtle changes of emphasis that we proposed were accepted, on broader issues we were often faced with a strong resistance that amounted to arrogance. One of the fundamental problems of the whole exercise was that the authors had little knowledge of prostate cancer.

Eventually relations between us, the Charter for Action team, and Revision Team broke down. Our proposed restructuring of the guidance, intended to make it more likely to be read, was rejected and we were told that no more meetings of the working group would take place, and that they regarded our contribution as complete.

We complained that the process was most unsatisfactory, and as a peace gesture, Mike Richards offered us the opportunity of including, with the Guidance, an *Insert* badged by the Charter, explaining the "societal" issues and why we thought they were important. After consultation with representatives of a number of Prostate Cancer Support Federation member groups, I concluded that we could not support anything that implied endorsement of the revised guidance as it stood, and, having failed to get suitably strong wording accepted, I withdrew from the process.

At a subsequent PCAG meeting, after general self-congratulation by all concerned that the pack was very nearly for issue, I made it very clear that this was happening against the wishes of patients, and promised that patients groups throughout the country would do all they could to influence GPs to ignore the very flawed guidance. After the meeting, a very well respected clinician, who for reasons of his own protection must for the moment remain nameless, suggested that if the Federation feel as strongly as my statement suggested, it should publish its own version of the PCRMP putting the simple facts before GPs. He

hinted that he might endorse such a document?

The Real Prostate Cancer Risk Management Programme

So that is what we are going to do. We are in the course of preparing a simple leaflet, supported and vetted by eminent clinicians, and aimed both at GPs and men in general, which will give the unbiased facts about the PSA Test, and provide, as the official PCRMP should provide but doesn't, straight forward advice about what a GP should say to a symptomless man who asks for a PSA Test. This is, basically, "Yes, but be aware of the following ...", followed by 7 points that have already been agreed by the Federation Trustees as summing up the position on PSA Testing. This will be called the 'Real Prostate Cancer Risk Management Programme', and will fit on a single sheet of paper. We hope that, faced with the alternative of reading the official document, weighing in at approximately 30 pages, GPs will read ours. But we need to move fast.

We plan to have the leaflet designed and printed within the next few weeks. Of course, we cannot compete with the DH and mail every GP in the country with our simple message, so we are relying on patients, who are members of Federation member groups, to distribute them in large numbers to their GPs and other health care providers.

To back up the campaign we have acquired the domain name, **www.pcrmp.org.uk**. The site is currently in the course of design, and we expect it to go live in an initial version in a few weeks.

If you feel you can help, please write to: The Real Prostate Cancer Risk Management Programme, PO Box 66, Emsworth, Hants, PO10 7ZP, or email:

realpcrmp@pcrmp.org.uk requesting copies of the leaflet, and we will send them to you as soon as we have them to hand.

With your help, perhaps we can undo some of the damage being done by the Department of Health.

The Breuss Diet

following his article in PM2, Rod Lane continues describing his dietary experiments

This article describes my experimentation with the Breuss Diet that consists of a 6 week juice fast that allows consumption of only a limited amount of vegetable juice and certain herb teas each day. During these experiments PSA, weight and other factors are monitored to assess its effect on disease progression and general health. Details of the Breuss Diet are shown opposite.

Experiment 1: Conducted 9th April – 21st May 2007

Great care was taken to follow the diet as rigidly as possible. Breuss allowed considerable flexibility in the preparation of the juices. They could be prepared daily by the patient (or his/her helper) or they could be purchased ready prepared from local health food shops. I decided to make fresh juice daily and to use, if possible, organic ingredients. Most of the ingredients for the herb teas could be obtained from local health food stores and those that could not were obtained by mail order. Details of suppliers are shown opposite.

From the reactions of relatives and friends who were part of the medical fraternity it was clear that what I was proposing to do was viewed with, to say the least, alarm. Although I was quite determined to proceed, I could see the desirability of some form of advice and counselling during the diet from someone, with experience and knowledge of diets and cancer. I selected as my mentor Mrs Susan Allshorn who was a herbalist and a Gerson Practitioner with experience of the Gerson Diet.

I visited Susan for an initial consultation and made arrangement for various tests to be done before and after completion of the diet to determine its effect on my general health – in particular a full blood analysis. PSA tests would be conducted as a part of my conventional hormone treatment (I still continued to have 3 monthly Zoladex injections). I was to monitor weight change and any unusual symptoms myself, which I would report and discuss with her.

Abstaining from food was much easier than expected, especially after the first couple of days, and there was little evidence of any loss of energy. The precise function of the herb teas has never been apparent, but they did serve a useful purpose in suppressing hunger. My starting weight was 11 stone 2lbs and I progressively lost weight during the diet. The final weight loss after 6 weeks was 20lbs, well within the limits indicated by Breuss (11-33lbs). Energy level remained good for the first 4 weeks, but I made a deliberate attempt to walk more slowly during the last couple of weeks of the diet. My blood pressure, which was always on the low side of normal, did not alter during the diet and the blood sugar remained within the normal range. Further, the full blood analysis, which showed no problem at the start of the diet, was also quite

satisfactory after it was concluded.

The last PSA before the start of the diet was 83 conducted on 19/03/07. The PSA was tested again on 24/05/07 three days after the diet had been completed by which time it had dropped dramatically to 53. I believe everybody was surprised the diet had produced such a dramatic decrease in PSA giving, effectively, a period of remission. I did not however, believe that my cancer had been 'cured', but a remarkable degree of disease regression had been experienced – a most gratifying result.

During the week following completion of the diet, as expected, the PSA value began to increase again; it would seem that likely this was slow at first, but with a progressive acceleration in the rate of rise in PSA. In the weeks between PSA tests on 30/07/07 and 15/08/07 the PSA exceeded 100 and was rising very rapidly. At this point I decided to begin a second Breuss Diet, which is described in the next section.

Clearly what was done after completion of the Breuss Diet was as important as what happens during the diet itself. At this point I began to look very critically at my eating pattern following the diet. In addition to realizing the possible necessity of eliminating the 'mistakes' that I had allowed, I began to look at the sheer amount of food that I had been consuming. During the 5 days after completion of the Breuss diet my weight increased by 8-9 lbs.

Experiment 2: Conducted 15th Aug – 27th Sept 2007

The second Breuss diet was accompanied by closer monitoring of the PSA. In this case PSA was measured on the first and last day of the diet to avoid the uncertainties of 'estimation by extrapolation'. The PSA was also measured close to the halfway point on 06/09/07. In the two weeks before the second Breuss Diet was started the PSA was rising rapidly, at a rate much higher than at the start of the first Breuss Diet. This might have been due in part to serious deficiencies in my vegan diet between 21/05/07 and 15/08/07.

During May and June significant new information was obtained from the Prostate Cancer Support Group – PCaSO concerning diets for hormone dependent cancers. Professor Jane Plant, a geochemist at Imperial College and a former breast cancer patient, gave a talk at one of the group meetings. All diets that I had been experimenting with since 2003 excluded or severely limited all animal produce, including dairy, but for the first time Professor Plant had brought the rationale for the exclusion of dairy into the general public domain. The fact that the problem with dairy was well known in certain scientific circles but, remained unknown to the general public, including clinicians, raises profound questions, which are discussed in Professor Plants books.

Although I was supposed to be completely avoiding dairy produce my avoidance was not absolute and during the period following the first Breuss Diet I was perhaps particularly lax. In the future, presented with the scientific rationale for excluding dairy, the ban would be much more rigorously applied. Perhaps significantly, during the Breuss Diet dairy was totally excluded, which could be another reason for its success.

The PSA readings during the second Breuss experiment were initially disappointing. At the start of the diet on 15th Aug. 07 the PSA was 114. Half way through the diet on 6th Sept. 07 it had risen to 126. I initially felt disheartened, but when I examined the data in more detail I noted the very high rate of rise immediately before starting the second experiment and the much smaller rate of rise of PSA during the Breuss Diet. I now awaited the reading at the end of the diet on 26th Sept 07 and was gratified to see a fall in PSA to 117. This effectively meant that there had been no significant increase in PSA during the 6 weeks diet period.

On completion of the juice fast, I resumed my 'near vegan' diet although more strictly controlled by reduced calorie intake. I expected to see the PSA immediately rise again, but I had a pleasant surprise, the PSA had continued to fall reaching 77 on 11 Oct. 07. However by 23rd Nov. 07 another PSA test indicated a rise to 127. The substantial fall in PSA, due to the Breuss Diet, followed by a rapid rise was similar to that observed in the first experiment. My attempt to reduce the rate of rise in the second experiment by controlling calorie intake during the 'near vegan' phase had not succeeded, suggesting a much more restrictive vegan regime, following the juice fast, was needed.

Conclusions I concluded that the Breuss diet could produce a considerable reduction in PSA and, presumably, disease progression. Since the Breuss Diet could not be undertaken continuously, to produce longer-term benefits it required to be operated in conjunction with another diet regime to restore body weight. The cyclic regime adopted here has shown that the PSA can be held in check for a period of up to 260 days. Further experiments will be needed to see if benefits could be extended over a longer period.

Subsequent Experiments Between Dec 07 and Jan.09 I have conducted further dietary experiments, suggesting that complementary diets therapies, in conjunction with conventional hormone and steroid treatment, may prevent disease progression for up to 2 years after the conventional treatments alone have become ineffective. These further experiments are ongoing and the results will be reported on completion.

Rod Lane

Breuss Diet Instructions

Preparation of Juice

600g beetroot
200g carrots
200g celeriac
60g radish

Preferably prepare juice each day using a low speed juicer/ grinder to avoid degradation of juice. Adjust the amount of vegetables to give half a litre (500ml) of juice per day – the amount of juice may vary depending on the juicer and the vegetables.

The Herb Teas

Sage Tea -

I used half a litre per day prepared by first boiling 2 bags of sage tea in half a litre of water for three minutes and then adding one bag each of peppermint tea, lemon balm tea and St. John's wort tea and boiling for ten minutes. There was no restriction on the amount of sage tea to be consumed and there was encouragement to consume more.

Kidney Tea - Prepared by mixing:

15g horsetail, 10g stinging nettle,
8g knotgrass, 5g St. John's wort.

I used no more than one and a half cups prepared by placing one table spoon of kidney tea in half a cup hot water for ten minutes, straining to remove the leaves, setting aside the liquid, boiling the leaves in one cup of water for ten minutes and adding to the liquid that was set aside.

Cranesbill Tea - I used half a cup per day, prepared by allowing half a table-spoon of cranesbill root to steep in hot water for ten minutes (the herb could not be obtained).

Small Flowering Willow Herb Tea

(for prostate cancer only)

I used one cup per day prepared by allowing one tablespoon to steep for ten minutes in hot water.

The following teas were available from local health food shops:

Sage, Peppermint, Lemon Balm, St. John's wort, and Stinging Nettle.

Cranesbill root can be obtained from: Phyto Products Ltd, Park Works, Park Road, Mansfield Woodhouse, Notts, NG19 8EF.

Small flowering willow herb can be obtained from: G. Baldwin & Co, 171-173 Walworth Rd, London, SE17 1RW.

Taking the Juice and Teas

I took half a cup of juice in the early morning after some of the teas and the rest during the day as needed. I never took more than half a litre, but sometimes less.

Please note, that the above instructions were the ones that I employed. They were based on the instructions given by Ralph Breuss in his book 'The Breuss Cancer Cure' It is recommended that anyone undertaking the diet should obtain the book, which has further instructions. See Reference 4 >>

Diets and Cancer by Rod Lane

The Macrobiotic Diets (Reference 1)

The Macrobiotic Diets originated in the Far East and particularly in Japan. It is known from epidemiological evidence of cancer rates in different populations that far eastern countries have much lower cancer rates for most types of cancer than western countries and this has been attributed to their diets which, unlike the western diet, do not depend on the consumption of large quantities of meat and dairy produce. The macrobiotic diet emphasizes: less processed, more natural, organic, locally grown food and in this respect it corresponds closely to vegan diets already described. The diet consists of meals prepared according to the balance between yin and yang properties and the metabolic diet is a part of a complete lifestyle, which emphasizes the necessity to strive for balance and living in harmony with nature and the physical surroundings. Extremely yin foods include very sweet foods, dairy produce and coffee while extremely yang foods include very salty food and red meat. The avoidance of extreme yin and extreme yang food in practice means that the macrobiotic diet has little meat or dairy produce and avoids sugar and salt. In consequence although the macrobiotic diet is not strictly a vegan diet, in practice it is very similar to the vegan diets and therapies being promoted in the west.

The Plant Programme (Reference 2)

Professor Jane Plant of Imperial College, London has recently provided an important contribution to the development of diets for cancer. She was a cancer sufferer herself who recovered from breast cancer after modifying her diet, which she used as a complementary treatment to traditional chemotherapy. Professor Plant emphasized the need to eliminate dairy produce and justifies her assertion by a survey of peer-reviewed literature, which identifies the growth factors and hormones in dairy produce as cancer promoting agents. Previous vegan diet treatments for cancer had almost universally prohibited dairy produce, but Professor Plant provided the very necessary scientific background to justify this prohibition and encourage the resolve to see it implemented. It is most remarkable that the evidence, supporting the prohibition of dairy, should have been found in peer reviewed scientific papers that had been largely ignored; this highlights the fact that the cancer problem is not merely scientific, but has crucial financial and political dimensions. This state of affairs had also long been suspected but definitive evidence was lacking.

Professor Plant has written several books that provide detailed dietary guidance to sufferers of hormone related cancers. They also provide the medical, scientific, political and financial background in a comprehensive but readable form suitable for the general reader, the clinician and the scientist. Many important questions are raised, which require to be answered.

Diet Programmes from the Bristol Cancer Centre, now called the Penny Brohn Centre (Reference 3)

Penny Brohn, another cancer sufferer herself, helped to establish the Bristol Cancer Centre which was not associated specifically with any particular diet but gathered knowledge on all alternative and complementary diet treatments in order to provide advice to patients and identify a diet to suit their needs. Following criticism from the cancer charities the Centre was nearly closed and only survived after legal action established that the criticisms were not justified. The Centre is still active today and currently focuses particularly on complementary diet therapies for use in conjunction with conventional cancer treatments. It has consequently established a very good relationship with many conventional medicine practitioners.

References:

- 1 Horowitz J. and Tomita M. 'The Macrobiotic Diet as Treatment for Cancer: Review of the Evidence', Complimentary and Alternative Medicine Vol. 6, No. 4 (2002). <http://xnet.kp.org/permanentejournal/fall02/macrobiotic.html>.
- 2 Plant J. 'Prostate Cancer: Understand, Prevent and Overcome' (2004, Virgin Publishing Ltd, London). ISBN 1-85227-188-4.
- 3 Penny Brohn - *The Bristol Approach*, developed by doctors, nurses, therapists and people with cancer, is a unique combination of complementary therapies and self-help techniques. Helpline 0845 123 2310 <> www.pennybrohncancercare.org
- 4 Breuss R, 'The Breuss Cancer Cure' (1995, Alive Books, Burnbury BC, Canada). ISBN 0-920470-56-4.

Clinical Trial

STAMPEDE - Systematic Therapy in Advancing Metastatic Prostate cancer: Evaluation of Drug Efficacy

Study Design

STAMPEDE is a multi-arm multi-stage international randomised controlled trial to assess the safety and effectiveness of treatment with hormone therapy using three additional drugs, docetaxel, zoledronic acid and celecoxib. Docetaxel (Taxotere) is a chemotherapy drug that is now used to treat those with advanced prostate cancer and is available on the NHS; zoledronic acid (Zometa) slows the release of calcium from the bones and may protect them; celecoxib (Celebrex) is an aspirin-like drug that has been mainly used as a relief for arthritis and may affect the cancer.

Eligibility Criteria

The trial is for men newly diagnosed with advanced prostate cancer, including those where the cancer has spread to the bones. It may also suit some previously treated men who may have PSA doubling times of less than six months.

The trial is open to recruitment across the UK and is expanding at the moment with more centres coming on board.

Study Centres

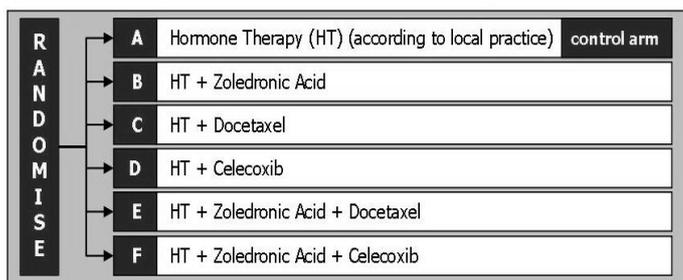
If you would be interested to join this trial, you should discuss your situation with your consultant and ask to be referred to one of the participating hospitals. Some people join trials because they feel that they might benefit more from the treatments under study; some people join trials because they want to help men like themselves in the future; some people join trials because they feel that their condition will be monitored more closely (and at no extra cost to themselves). Any man who joins a trial can leave the trial at any time.

With around 800 patients registered to date, the trial has now moved from the Pilot phase to the Efficacy Stage I. The eventual target is to recruit about 3,300 patients. The trial is run from the Medical Research Council Clinical Trials Unit and is funded by Cancer Research UK.

Study Arms

The figure below shows the five research 'arms' that will be used. Together with the 'Control arm' (i.e. those on standard hormone therapy treatment only).

Design: Multi-arm multi-stage randomised controlled trial with 5 experimental arms and 5 stages.



Purple GMO Tomato Inferior to Nature's Offerings

In what appears to be an attempt at softening the public's attitude toward genetically-modified organisms (GMOs), British scientists have engineered a purple tomato, rich in antioxidants, by splicing certain genes from the snapdragon flower with those of a tomato in order to create a "super tomato" that they say may fight cancer. But do these findings tell the whole story? Of the hundreds of worldwide sources that reported these findings, some honestly side-noted that *natural tomatoes* already have cancer-fighting properties, also mentioning that natural, unmodified fruits such as blackberries, blueberries, currants, and a host of other dark red and dark purple fruits already contain high levels of cancer-fighting anthocyanins. Others were not so forthright, shrouding nature in inferiority as this "franken-fruit" was hoisted to miracle status.

Ethan Huff - *Natural News* Oct.08

Spinning the Truth About the Halted NCI Prostate Cancer Study

The National Cancer Institute has announced a halt to its \$114 million study of whether vitamin E and selenium can prevent prostate cancer, saying that they cannot and that they might even cause slightly elevated risks for more prostate cancer and diabetes. However, upon further examination it becomes apparent that the study was flawed to begin with due to the forms of vitamin E and selenium chosen for the study. Instead of the natural forms of the two supplements, the study opted to use a synthetic petroleum based form of vitamin E and a form of selenium derived from industrial

ore processing byproducts. The flawed study also illustrates how easy it is to manipulate studies on natural alternatives to the highly profitable drugs and treatments of mainstream medicine.

The safety panel for the 35,000-man study called SELECT (SELenium and vitamin E Cancer prevention Trial) called for a halt when an early look at the data showed no benefit for the treatment. Study participants were told to stop taking the two pills they'd been taking every day since the trial opened in 2001.

Previous and even larger studies showed that taking vitamin E resulted in a 32% lower rate of prostate cancer and taking selenium resulted in a 60% lower incidence of prostate cancer.

How is it then possible that a new study would find no reductions, and even slight increases in prostate cancer as well as diabetes from taking a common vitamin and mineral? The answer is that it is not possible unless the study was flawed, perhaps deliberately so - which has been known to happen over and over when it comes to natural competition to patented drugs and treatments.

Tony Isaacs -Natural News Oct08

More evidence that fish prevents PCa

Canadian researchers report that men who eat fish several times a week may protect themselves from prostate cancer, while men who eat meat, ham or sausage 5 times a week may have a 3-fold increased risk of prostate cancer. These findings add to a growing body of evidence suggesting a relationship between diet and prostate cancer risk.

"Many studies have suggested that nutritional factors may affect prostate cancer development," says Armen Aprikian, MD. of the urology division McGill University Health Centre, Montréal, Que. "The aim of our study was to evaluate the relationship between dietary habits and prostate cancer detection."

His team studied 917 men who underwent biopsy because of elevated PSA level, rising PSA or abnormal DRE. All patients answered a self-administered food frequency questionnaire.

The association of a meat-heavy diet prostate with cancer was statistically significant, and so was the association of lower prostate cancer risk with fish-eating. In this group of 900 men who already showed signs of prostate problems, men who ate red meat or meat products almost every day (5 times a week) were 3 times likelier than average to have prostate cancer. Men at risk who ate fish 4 times a week were half as likely as average to have prostate cancer.

Canadian Urological Ass. J. Oct.08

Degarelix makes testosterone levels fall dramatically

FIRMAGON® (degarelix), is a new GnRH receptor antagonist indicated for patients with advanced, hormone-dependent prostate cancer. In Phase III studies degarelix produced a significant reduction in levels of testosterone within three days in more than 96% of study patients. Testosterone plays a major role in the growth and spread of prostate cancer cells.

The data shows that degarelix provided an extremely fast effect on testosterone levels, close to the immediate effect achieved with surgery (orchidectomy).

The Phase III study of 610 men compared monthly administration of *degarelix* with monthly luteinising hormone releasing-hormone (LHRH) agonist *leuprorelin*. By day 3 of the study, testosterone levels were suppressed to $\leq 0.5\text{ng/mL}$ in 96.1% of patients in the degarelix arms of the study compared to 0% in the leuprorelin arm. By day 14, 100% of patients in the degarelix arms achieved suppression of testosterone levels at $\leq 0.5\text{ng/mL}$ compared to 18.2% in the leuprorelin arm. After 14

days of treatment, PSA levels had declined in the degarelix treated patients by a median of 64%, while patients who were administered leuprorelin saw an 18% decline. Both treatments were well tolerated and showed similar side effect profiles. The most common side effects of degarelix are hot flushes, injection site pain, injection site erythema, increased weight, nasopharyngitis, fatigue and back pain.

"Our goal is always to have a fast and sustained reduction in testosterone levels" said Mr John Anderson, Consultant Urological Surgeon, The Royal Hallamshire Hospital, Sheffield, "Degarelix produces an extremely rapid impact, approaching the immediacy of surgery and it is good news that the product should become imminently available."

Ferring Pharmaceuticals plans to launch FIRMAGON® (degarelix) in Europe in the first quarter of 2009 and has just received FDA approval for commercialisation in the US. It is expected that commercialisation in other key global markets will follow.

Free prescriptions for cancer patients

Cancer patients are entitled to free prescriptions from 1 April 2009. All cancer patients undergoing treatment for cancer, the effects of cancer or the effects of cancer treatment are now encouraged to apply for exemption certificates from their GP surgery or oncology clinic now. Applications for certificates received by 24 March will be processed in time to be used by 1 April. Patients who do not receive their certificate in time will be able to get a refund for any prescription charges they have paid since 1 April.

Exemption certificates last for 5 years, (but can be reapplied for), and cover all prescriptions, not just those relating to cancer. If you have a cancer diagnosis all your prescriptions will be free, including those for cancer, as a consequence of cancer, or unrelated to cancer.

European Prostate Cancer Coalition - EUROPA UOMO by Mike Lockett

Europa Uomo (EU) started in Rome in 2002, and was legally established in Milan in June 2004. It is a European coalition of patient support groups for prostate diseases in general and prostate cancer in particular. Full membership is open to European countries as defined by the World Health Organisation as well as to any country that is a potential candidate for admission to the European Union. EU is the European advocacy movement for the fight against prostate cancer. Its aims at a European level are similar to those of the Federation in the UK, which include (among others):

- to bring the power of the combined patient voice to bear on those in authority;
- to increase awareness;
- to emphasise the need for early detection
- to improve treatment standards for patients and carers.

The Prostate Cancer Support Federation is the UK member of EU and is represented on the steering committee.

To establish an international organisation and to enable it to grow requires support, good will and funding. EU was fortunate to have support from Dr Alberto Costa, a Director of the European school of oncology, Milan. Dr Costa is also the coordinator of breast cancer units in Milan and Lugarno, Switzerland and had worked with Europa Donna, the European breast cancer coalition. He had witnessed the major achievements of Europa Donna at international and national levels and gave his support to the male equivalent organisation Europa Uomo.

Since its inception EU has grown to twenty-one member countries and has also established a Scientific Committee, a feature which I would like to see emulated by the Federation. Leading experts in prostate cancer (from Holland,

Sweden, Spain, Germany, Italy and the UK) were invited to join the committee to advise EU on treatment developments and to act as a "sounding board" for EU ideas. Each member of the scientific committee is a supporter of patient advocacy and of the role of our organisation.

EU is now recognised as a significant voice and is receiving a growing number of invitations to express the views of prostate cancer patients. Typical of these has been the association with the EAU (European Association of Urology), which represents more than 16,000 urology professionals across Europe (many from the UK) and worldwide. Its mission is to raise the level of urological care in Europe. EU has been invited to have an exhibition stand and will be represented at the EAU annual congress in Stockholm in March 2009.

At the UICC World Cancer Congress in Geneva in 2008, EU, along with representatives of patient groups from USA, Canada, Australia and New Zealand got prostate cancer on their agenda as a focused cancer for the first time with two major sessions dedicated to this disease.

Exposure creates exposure, and representatives of EU have been included in activities of other groups such as ESMO (European Society for Medical Oncology), European Parliament health forums and many pharmaceutical companies have realised the benefit of engaging with patient groups, which has led to EU being invited to events organised by Astra Zeneca, GlaxoSmithKline and Ferring.

EU is developing an active lobbying campaign to present prostate cancer issues to European parliamentarians. Currently (thanks to the work of Europa Donna) there is a European parliamentary group on breast cancer and a European parliament breast cancer resolution - EU is determined to achieve the same

level of focus on and commitment to prostate cancer.

In the latter part of 2008 EU has been actively represented in a number of oncological events including the following:

- Prostate Histoscanning: medical advisory board meeting London, Nov. 5-6, 2008 (L. Denis)
- Europa Donna advocacy workshop training course Milan, Nov. 7-9, 2008 (T. Hudson - L. Denis)
- Prostate cancer patient advocacy group summit Paris, Nov. 21, 2008 (10 EU representatives invited including M. Lockett, UK)
- EPPOSI general assembly - L. Denis elected as board member representing Europa Uomo. Brussels, Nov. 26, 2008
- Hormone Refractory PCa Multi-disciplinary Network Meeting 2008 Manchester; Nov. 28, 2008 (T. Hudson - M. Lockett)
- meeting AstraZeneca Global London, Dec. 9, 2008 (T. Hudson - L. Denis)

On December 12, 2008 EU received an ESO grant of 5.000 euro to further develop its website.

Last but not least the EU chairman Tom Hudson obtained an educational grant for a training session in Krakow (Poland) at the beginning of February 2009. Its purpose will be to assist some of the Eastern European countries to establish support organisations and services in their countries.

EU has high expectations of further development into a single European voice for patient advocacy in prostate cancer. We have the support of the professional organisations and are getting closer to pharmaceutical company support for a number of our projects.

Mike Lockett

PCSF representative to Europa Uomo

General Disclaimer This newsletter is providing news, information, personal memoir and opinion about prostate cancer. It also reports, quotes and cites published medical views and research findings about prostate problems. Anyone who wishes to embark on any dietary, drug, exercise or other lifestyle change intended to prevent or treat a specific disease or condition should first consult with and seek clearance from a qualified health care professional.