

A randomised double blind evaluation of an antioxidant rich dietary food supplement versus placebo in men prostate cancer

Introduction. Epidemiological and large cohort studies support the paradigm that antioxidant-rich diets reduce the risk of prostate cancer (Giovannucci et al 2002). More recently prospective studies show that diet and lifestyle may also benefit men with established disease by slowing or halting PSA progression (Ornish 2005). Prospective studies have demonstrated a prolongation in doubling time after starting antioxidant rich food supplements but to date there are no randomised trials evaluating the impact of antioxidants on PSA dynamics. Antioxidants are thought to wield their anti-cancer properties by counterbalancing the superoxide free radicals produced from our environment (Chen 2001, Stivala 2000). Although patients with established prostate cancer have already sustained DNA damage in order to mutate from benign to malignant cells, avoiding further DNA insults may avoid further mutations of indolent malignant or pre-malignant cells into more aggressive phenotypes (Chan 2005; Sonn 2005). The antioxidants in most cases are not denatured on drying so concentrating the food into a capsule is a convenient way to increase daily intake.

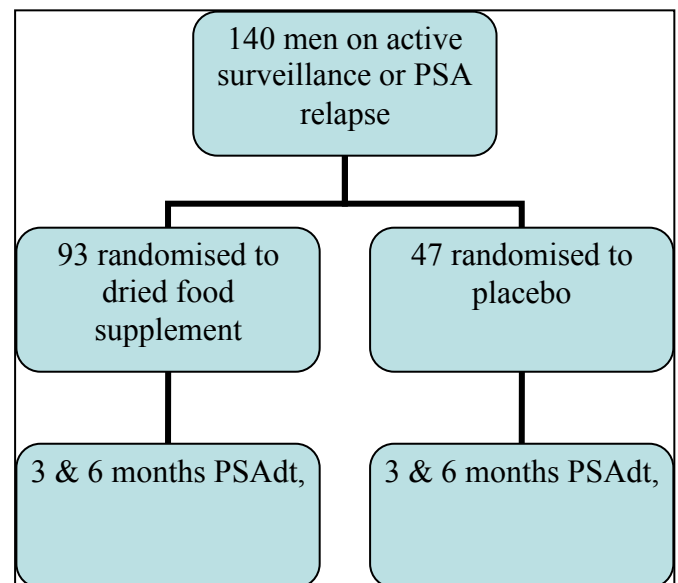
Aims: To establish whether boosting the diet with an antioxidant-rich food supplement has an influence on PSA progression compared to placebo.

The intervention: A dried food capsule composed of green tea, pomegranate, broccoli and curcumin. The foods chosen to test this hypothesis have; demonstrated influence on prostate cancer either in epidemiological, laboratory or prospective studies; have a good safety profile; provide a wide range of natural antioxidants as they originate from different food types.

Cohort: Men with prostate cancer suitable for active surveillance.

Methodology: A double blind placebo controlled randomised trial. Following written informed consent, men will be randomised between food supplement versus placebo (2:1).

Trial end points: Tolerance to the supplement. PSA doubling time measured at 3 and 6 months from baseline between the intervention group and placebo;



Principal Investigator: Professor Robert Thomas MRCP MD FRCR
Consultant Oncologist, Cranfield University, Bedford & Addenbrooke's, NHS Hospital Trusts.

Co-ordinating centre: The Primrose Unit, Bedford Hospital, Bedford MK42 9DJ. Tel: 44 (0) 1234 795 787, Fax: 44 (0) 1234 792 668, Email: rt@cancernet.co.uk

Manager: Madeleine Williams. **Statistician:** Pat Bellamy **Trials nurses;** Anne Willis

References: see full protocol