The ProtecT Trial - Evaluating the Effectiveness of Treatments for Clinically Localised Prostate Cancer

Introduction and Objective: Prostate cancer is a significant public health problem with around 899,000 cases diagnosed worldwide. Intense debate surrounds the appropriate treatment, in part due to the absence of randomised trials comparing contemporary treatments. We have designed and conducted a trial of three major prostate cancer treatments.
Materials and Methods: The ProtecT randomised trial compares the effectiveness, cost-effectiveness and acceptability of treatments for localised prostate cancer preceded by community-based PSA testing in primary care. The trial compares active monitoring (regular disease assessments including PSA tests), radical prostatectomy and radical conformal radiotherapy. Unselected men aged 50-69 years were invited from 9 centres across the UK. The trial primary outcome is disease-specific survival at 10 years with secondary outcomes of overall survival, disease progression, treatment complications, urinary symptoms, sexual function, QoL and health service utilisation.
Results: Over 80,000 men participated (35% of invited) in the trial (2002-2009) and over 8,500 had a PSA of 3 ng/ml or above (10%, the biopsy threshold but PSA ≥20 ng/ml excluded). Nearly 7,500 men underwent biopsies (88% of eligible) and nearly 3,000 men were diagnosed with prostate cancer of which 2,500 had localised disease (35% of raised PSA). 1643 men were randomised (61% of eligible) giving over 500 participants in each treatment group. The clinical characteristics of randomised participants was generally favourable (Table 1). Follow-up is currently a median of 7 years with over 90% follow-up for the secondary outcomes and over 98% for the primary outcome.
Conclusions: This large trial comparing three prostate cancer treatments will have a major impact on future clinical practice worldwide. The demographic and clinical characteristics of randomised participants are very comparable to those of men diagnosed currently through prostate cancer screening.

Table 1 Clinical and demographic characteristics of participants at randomisation

Characteristic	Category	Randomised (%) (n = 1643)
Age (years)	50-54 55-59 60-64 65+	144 (8.8%) 372 (22.6%) 518 (31.5%) 609 (37.1%)
PSA (ng/ml)	3.0-5.99 6.0-9.99 10.0-19.99	1126 (68.5%) 357 (21.7%) 160 (9.7%)
Gleason score	6 7-10	1266 (77.1%) 376 (22.9%)