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Prostate Testing for Cancer and Treatment (ProtecT) Feasibility Study

Submission date	Recruitment status	[_] Prospectively registered
20/11/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/11/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/09/2012	Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.epi.bris.ac.uk/protect/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 96/20/06

Study information

Scientific Title

Acronym
ProtecT

Study objectives
The overall aim was to evaluate the feasibility of a randomised controlled trial (RCT) of treatments for localised prostate cancer, including:
1. Feasibility of case-finding in the community (including the reliability and psychosocial impact of PSA testing)
2. Determining the most efficient and effective design for a major trial of treatments
3. Randomised trial of recruitment strategies
4. Piloting outcome measures and procedures for the main trial of treatments

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Patient information can be found at: http://www.epi.bris.ac.uk/protect/takingpart/takingpart.htm

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
The study was an RCT of treatment preceded by case-finding in the community, with qualitative research methods integrated at each stage. Men with confirmed localised prostate cancer were

asked to consent to randomisation between a nurse or urologist for an information appointment to discuss recruitment to the treatment trial. In the information appointment, the need for a trial was explained in detail, along with the advantages and disadvantages of each treatment, and the recruiter attempted to randomise the patient to the treatment trial or reach a patient-led preference for a treatment. All men, whether randomised or not, were asked to consent to be followed-up, and these formed a pilot for the proposed main trial.

See details of ProtecT main trial on http://www.controlled-trials.com/ISRCTN20141297

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary outcome was the proportion of patients accepting randomisation to the treatment trial. Number of eligible patients randomised by nurses and urologists

Secondary outcome measures
Cost effectiveness of nurses and urologists

Overall study start date
01/06/1999

Completion date
31/05/2001

Eligibility

Key inclusion criteria
Men aged 50-69 years from specific primary care centres in the three cities were invited to attend a 30-minute prostate check clinic appointment in which they were informed about the study and asked to consent to a prostate specific antigen (PSA) test. Men with a raised PSA (initially ≥3.0 ng/ml if 5059 years; ≥4.0 ng/ml if 6069 years; but changed to ≥3.0 ng/ml for all men after 1 year) were invited for biopsy. Men with confirmed localised prostate cancer were invited to participate in a randomised trial of recruitment strategies.

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
150

Key exclusion criteria
Men considered by the GP to be unfit for any of the potential treatments (ie those terminally ill or with serious co-morbidity).

Date of first enrolment
01/06/1999

Date of final enrolment
31/05/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Social Medicine
Bristol
United Kingdom
BS8 2PR

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/10/2002		Yes	No
Results article	results on patients' perceptions of randomisation and reasons for consent or refusal to participate in the ProtecT study	01/06/2003		Yes	No
Results article	results on the effectiveness of nurses and surgeons in recruiting patients	01/07/2003		Yes	No
Other publications	HTA monograph	01/10/2003		Yes	No