

Prostate Testing for Cancer and Treatment (ProtecT) Feasibility Study

Submission date 20/11/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/11/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/09/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

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 50-59 years; ≥ 4.0 ng/ml if 60-69 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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Sheila.Greener@doh.gsi.gov.uk

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