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The ProtecT trial - Evaluating the effectiveness of treatment for clinically localised prostate cancer

Submission date 14/10/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/10/2002	**Overall study status** Ongoing	
Last Edited 10/05/2023	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-treatment-approaches-for-prostate-cancer

Study website
http://www.bris.ac.uk/social-community-medicine/projects/protect/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00632983

Secondary identifying numbers
HTA 96/20/99

Study information

Scientific Title
The ProtecT trial - Evaluating the effectiveness of treatment for clinically localised prostate cancer

Acronym
ProtecT

Study objectives
Current hypothesis as of 18/03/2019:
The overall aim is to evaluate the effectiveness, cost-effectiveness and acceptability of treatments for men with localised prostate cancer within the context of a pragmatic randomised controlled trial. This will compare three treatments (active monitoring, radical prostatectomy and radical radiotherapy). Specific objectives are as follows:
1. To assess survival at 15 years following treatment.
2. To investigate a number of medium-term outcomes, including: disease progression (biochemical and clinical), treatment complications, lower urinary tract symptoms, psychosocial impact of treatment, including generic health status, quality of life and sexual function.

Previous hypothesis as of 14/08/2013:
The overall aim is to evaluate the effectiveness, cost-effectiveness and acceptability of treatments for men with localised prostate cancer within the context of a pragmatic randomised controlled trial. This will compare three treatments (active monitoring, radical prostatectomy and radical radiotherapy). Specific objectives are as follows:
1. To assess survival at 10 years and 15 years following treatment
2. To investigate a number of short and medium-term outcomes, including: disease progression (biochemical and clinical), treatment complications, lower urinary tract symptoms, psychosocial impact of case-finding and treatment, including generic health status, quality of life and sexual function
3. To estimate the resource use and costs of case-finding, treatment and follow-up, and to compare costs and outcomes of treatment in terms of survival and health related quality of life.

Previous hypothesis:
The overall aim is to evaluate the effectiveness, cost-effectiveness and acceptability of treatments for men with localised prostate cancer within the context of a pragmatic randomised controlled trial. This will compare 3 treatments (active monitoring, radical prostatectomy and radical radiotherapy). Specific objectives are as follows:

1. To assess survival at 5, 10 years and 15 years following treatment
2. To investigate a number of short and medium-term outcomes, including: disease progression (biochemical and clinical), treatment complications, lower urinary tract symptoms, psychosocial impact of case-finding and treatment, including generic health status, quality of life and sexual function
3. To estimate the resource use and costs of case-finding, treatment and follow-up, and to compare costs and outcomes of treatment in terms of survival and health related quality of life.

Details of this study can also be found at: https://www.journalslibrary.nihr.ac.uk/programmes/hta/962099/#/
Protocol can be found at: https://njl-admin.nihr.ac.uk/document/download/2007358

Ethics approval required
Old ethics approval format

Ethics approval(s)
Trent Multicentre Research Ethics Committee (Trent MREC), 21/06/2001, ref: 01/4/025

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: https://www.bristol.ac.uk/population-health-sciences/projects/protect/

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

Interventions
Current interventions as of 14/08/2013:
1. Radical prostatectomy
2. Radical radiotherapy
3. Active monitoring: monitoring of the disease including prostate specific antigen levels

Previous interventions:
1. Radical prostatectomy
2. Radical radiotherapy
3. Active monitoring of prostate specific antigen (PSA) levels

See details of ISRCTN08435261: ProtecT feasibility on http://www.isrctn.com/ISRCTN08435261 and details of ISRCTN92187251: The CAP (Comparison Arm for ProtecT) study on http://www.isrctn.com/ISRCTN92187251

Intervention Type
Mixed

Primary outcome measure
Current primary outcome measures as of 18/03/2019:
1. Disease-specific survival at 15 years.
2. Disease progression (biochemical and clinical).
3. Treatment complications (long term).
4. Lower urinary tract symptoms.
5. Psychosocial impact of treatment including generic health status, quality of life and sexual function.
6. Prostate cancer specific survival.
7. Overall survival.

Previous primary outcome measures as of 14/08/2013:
1. Disease-specific survival at 10 years

Previous primary outcome measures as of 27/09/2010:
1. Disease progression (biochemical and clinical)
2. Treatment complications
3. Lower urinary tract symptoms
4. Psychosocial impact of case-finding and treatment including generic health status, quality of life and sexual function
5. Prostate cancer specific survival
6. Overall survival

Previous primary outcome measures as of 14/10/2002:
1. Disease progression (biochemical and clinical)
2. Treatment complications
3. Lower urinary tract symptoms
4. Psychosocial impact of case-finding and treatment including generic health status, quality of life and sexual function

Secondary outcome measures
Current secondary outcome measures as of 21/07/2021:
1. Overall survival
2. Disease progression (biochemical and clinical)
3. Lower urinary tract symptoms
4. Psychosocial impact of cancer diagnosis and treatment including generic health status, quality of life and sexual function
5. Cost-effectiveness of the treatments
15 year median analysis no health economic analysis

Previous secondary outcome measures added 14/08/2013:
1. Overall survival
2. Disease progression (biochemical and clinical)
3. Lower urinary tract symptoms

4. Psychosocial impact of cancer diagnosis and treatment including generic health status, quality of life and sexual function
5. Cost-effectiveness of the treatments

Overall study start date
01/06/2001

Completion date
31/03/2027

Eligibility

Key inclusion criteria
Men aged 50-69 years from the community, localised prostate cancer for eligibility for randomisation

Participant type(s)
Patient

Age group
Senior

Sex
Male

Target number of participants
116,500

Total final enrolment
8388

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/10/2001

Date of final enrolment
20/01/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

John Radcliffe Hospital
Oxford
United Kingdom
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Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Faculty of Medical Science
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Sponsor type
University/education

Website
http://www.ox.ac.uk

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Freddie C Hamdy (freddie.hamdy@nds.ox.ac.uk), anonymised data, 2023 indefinitely, request via a standard proforma to the ProtecT PIs to consider requests and can give the web link. consent was obtained

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes
Results article	results	01/10/2006		Yes	No
Results article	results	01/12/2007		Yes	No
Results article	results	27/04/2010		Yes	No
Results article	results	19/10/2010		Yes	No
Results article	results	01/11/2010		Yes	No
Results article	results	01/11/2010		Yes	No
Results article	results	15/01/2011		Yes	No
Other publications	case-control study	15/01/2012		Yes	No
Other publications	cross-sectional analysis	01/06/2012		Yes	No
Results article	active surveillance results	01/10/2012		Yes	No
Results article	acceptability results	01/12/2012		Yes	No
Results article	results	01/01/2013		Yes	No
Results article	results	01/09/2014		Yes	No
Results article	results	01/02/2015		Yes	No
Results article	results	18/09/2015		Yes	No

Results article	results	13/10/2016		Yes	No
Results article	results	13/10/2016		Yes	No
Results article	results	01/08/2017		Yes	No
Results article	results	01/04/2018	12/09/2019	Yes	No
Results article	results	01/09/2019	26/05/2020	Yes	No
Results article	results	01/09/2020	17/07/2020	Yes	No
Results article	10 year results	01/08/2020	13/08/2020	Yes	No
Results article	embedded qualitative study results	09/09/2020	11/09/2020	Yes	No
Results article	15 year results	11/03/2023	14/03/2023	Yes	No