

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

Submission date 14/10/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/10/2002	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/05/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-treatment-approaches-for-prostate-cancer>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00632983

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

Male

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**

United Kingdom

England

Study participating centre

John Radcliffe Hospital

Oxford

United Kingdom

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Sponsor information**Organisation**

University of Oxford (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, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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?
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
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
Other publications	case-control study	15/01/2012		Yes	No
Other publications	cross-sectional analysis	01/06/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes