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Cluster randomised triAl of PSA testing for Prostate cancer

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/11/2004	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 30/06/2025	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Screening for prostate cancer continues to cause controversy because of concerns about over-diagnosis and unnecessary treatment. The aim of this study is to help policy makers decide whether PSA testing for prostate cancer should be introduced by evaluating the effectiveness of PSA testing in reducing prostate cancer mortality (i.e. the number of deaths), and its cost-effectiveness (i.e. comparing the health-related costs in combination with the effectiveness of PSA testing, in order to assist policy makers in their decisions about how to achieve the best use of resources).

Who can participate?
Men aged 50 - 69 years from about 573 GP practices in eight UK centres (Sheffield, Newcastle, Bristol, Birmingham, Cardiff, Leeds, Cambridge and Leicester).

What does the study involve?
Participants will be randomly allocated to one of two groups. One group is invited to have a PSA test (population-based PSA testing) and the other group continues to receive standard NHS care in the UK, based on the NHS prostate cancer risk management programme. The study involves medical records being looked at by trained researchers working with local NHS Trusts. Trained researchers will put information about any tests or treatment received for prostate problems onto a computer, making sure no personal details (name, address etc.) will be recorded. Data will be identified only by a study number.

What are the possible benefits and risks of participating?
The study will have no impact on an individuals medical care. There are no direct benefits, although participation will contribute towards a better understanding of how prostate problems are currently diagnosed and managed by UK doctors.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
March 2004 to March 2016

Who is funding the study?
Cancer Research UK (CRUK) (UK)

Who is the main contact?
Prof Richard Martin

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-a-single-blood-test-for-prostate-cancer-cap

Study website
https://captrial.blogs.bristol.ac.uk/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Cluster randomised triAl of PSA testing for Prostate cancer

Acronym
CAP

Study objectives

Current hypothesis as of 06/08/2014:
The hypothesis under investigation is that population screening in the form of prostate specific antigen (PSA) testing of men aged 50 - 69 years reduces mortality from prostate cancer.

The objective of the study is to evaluate the effectiveness of population screening for prostate cancer by establishing a cluster randomised trial allocating general practices to either population-based PSA testing (the ProtecT trial, ISRCTN20141297) or unscreened standard practice in order to: provide an unbiased estimate of the effect of a single screening round for prostate cancer on prostate cancer-specific and all-cause mortality in the population, and to contribute to the international effort to investigate the impact of prostate cancer screening.

Previous hypothesis:
The hypothesis under investigation is that population screening in the form of prostate specific antigen (PSA) testing of men aged 50 - 69 years reduces the overall mortality from prostate cancer.

The objective of the study is to evaluate the effectiveness of population screening for prostate cancer by establishing a cluster randomised trial allocating general practices to either intensive case-finding (the ProtecT trial) or unscreened standard practice in order to: provide an unbiased estimate of the effect of a single screening round for prostate cancer on prostate cancer-specific and all-cause mortality in the population, and to contribute to the international effort to investigate the impact of prostate cancer screening.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Randomisation of practices into intervention (ISRCTN20141297) and control arms approved on 21/06/2001 (ref: MREC/01/4/025), also permitted follow-up of participants in the intervention arm. Multicentre Research Ethics Committee approval on 12/02/2004 (ref: MREC/03/4/093) gave permission for follow-up in the control arm, and review of medical records on 24/11/2005 (ref: 05 /MRE04/78).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Current interventions as of 06/08/2014:
General practices are randomised to participate in The ProtecT study (see ISRCTN20141297) or the control arm of the trial. In the ProtecT arm of the trial men are being invited to be tested for the presence of prostate cancer through population-based PSA testing. In the control arm men receive standard NHS care (NHS prostate cancer risk management programme).

Previous interventions:
Practices are randomised to participate in The ProtecT study (see ISRCTN20141297) or the comparison arm of the trial. In the ProtecT arm of the trial men are being invited to be tested for the presence of prostate cancer in a process of case-finding that is almost identical to population screening. In the comparison arm men are not subject to intensive case-finding for prostate cancer.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measure as of 04/02/2021:

Prostate cancer mortality at 15 years
See statistical analysis plan for further details: http://hdl.handle.net/1983/97a58ee2-e559-49e3-9029-954bd5dd5bd9
DOI: 10.17605/OSF.IO/7Y3G6

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Previous primary outcome measure:

Prostate cancer mortality at 10 years

Added 06/08/2014:
See statistical analysis plan for further details: http://hdl.handle.net/1983/6d41509f-ab93-4f96-9869-c320acbc4ae1

Secondary outcome measures
Current secondary outcome measures as of 04/02/2021:

Measured at 5 and 10, 15 and 20 years:
1. All-cause mortality
2. Disease status and staging
3. Cost-effectiveness: The projected lifetime effectiveness and cost-effectiveness of a range of UK-focused screening options, incorporating parameter estimates computed from CAP and

ProtecT data to create a UK-specific decision analytic model
4. Health-related quality of life
5. Age-specific lead-time and over-diagnosis rates (utilising observed trial data)

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Previous secondary outcome measures as of 06/08/2014:

Measured at 5 and 10, 15 and 20 years:
1. All-cause mortality
2. Disease status and staging
3. Cost-effectiveness
4. Health-related quality of life

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Previous secondary outcome measures:

Measured at 5 and 10 years:
1. All-cause mortality
2. Disease status and staging
3. Cost-effectiveness
4. Health-related quality of life

Overall study start date
01/03/2004

Completion date
01/03/2016

Eligibility

Key inclusion criteria
Current inclusion criteria as of 06/08/2014:
All men aged 50 - 69 years from 573 GP practices in eight UK centres (Sheffield, Newcastle, Bristol, Birmingham, Cardiff, Leeds, Cambridge, Leicester). An additional centre, Edinburgh, where routine data on cause of death did not undergo validation, will be included in a secondary analysis.

Previous inclusion criteria:
All men aged 50 - 69 years from approximately 400 GP practices in nine UK centres (Sheffield, Newcastle, Bristol, Birmingham, Cardiff, Edinburgh, Leeds, Cambridge, Leicester)

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
416,000

Key exclusion criteria
Current exclusion criteria as of 06/08/2014:
Inclusion criteria not met. Men identified as already having a prostate cancer diagnosis.

Previous exclusion criteria:
Does not meet inclusion criteria

Date of first enrolment
01/03/2004

Date of final enrolment
01/03/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bristol
Bristol
United Kingdom
BS8 2PS

Sponsor information

Organisation
University of Bristol (UK)

Sponsor details
Senate House
Tyndall Avenue
Bristol
England
United Kingdom
BS8 1TH

Sponsor type
University/education

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

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (refs: C11043/A4286, C18281/A11326, C18281/A8145 and C18281/A15064)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Statistical analysis plan at https://osf.io/7y3g6 (added 04/02/2021)

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/01/2008		Yes	No
	results				

Results article		01/04/2009		Yes	No
Results article	results	01/11/2010		Yes	No
Results article	results	01/11/2011		Yes	No
Results article	results	04/06/2013		Yes	No
Results article	results	10/06/2014		Yes	No
Results article	results	23/01/2015		Yes	No
Results article	results	29/04/2016		Yes	No
Results article	results	13/10/2016		Yes	No
Results article	results	06/03/2018		Yes	No
Plain English results			26/10/2022	No	Yes
Results article	prespecified secondary outcomes at 15-year follow-up	07/05/2024	30/06/2025	Yes	No