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European Randomised study of Screening for Prostate Cancer

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 12/04/2016	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.erspc.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR156

Study information

Scientific Title
European Randomised study of Screening for Prostate Cancer

Acronym
ERSPC

Study objectives
Screening causes a difference in prostate cancer mortality of 20% or more.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee gave approval

Study design
Multicentre randomised active-controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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

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

Interventions
Prostate Specific Antigen (PSA) determination followed by Digital Rectal Examination (DRE) and prostate biopsy if PSA greater than or equal to 3.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Prostate cancer mortality compared between the screened and the non-screened group of men at risk.

Secondary outcome measures
1. Progression-free (tumour free) survival
2. Survival free of metastatic disease
3. Quality of life in the screened and non-screened populations

Overall study start date
01/10/1991

Completion date
31/12/2010

Eligibility

Key inclusion criteria
Males aged 55 - 74 years (including age 74)

Participant type(s)
Patient

Age group
Senior

Sex
Male

Target number of participants
251133

Key exclusion criteria
Previous diagnosis of prostate cancer

Date of first enrolment
01/10/1991

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Belgium

Finland

France

Italy

Netherlands

Spain

Sweden

Switzerland

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

Sponsor details
Dr Molewaterplein 40/50
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Sponsor type
University/education

Website
http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Funder Name
European Union (EU) (Belgium) - Fifth and Sixth Framework Programmes (FP5, FP6)

Funder Name
The National Cancer Fund (Koningin Wilhelmina Fonds [KWF]) (Netherlands)

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	26/03/2009		Yes	No
Results article	results	01/08/2011		Yes	No
Other publications	11-year follow-up	15/03/2012		Yes	No
Results article	results	01/05/2012		Yes	No
Results article	results	01/11/2012		Yes	No
Results article	results	01/02/2014		Yes	No
Other publications	13-year follow-up	06/12/2014		Yes	No
Results article	results	01/08/2015		Yes	No