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Early vs delayed screening for prostate cancer

Submission date
13/01/2020

Recruitment status
No longer recruiting

Registration date
15/01/2020

Overall study status
Ongoing

Last Edited
18/11/2025

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Prostate cancer is the most commonly diagnosed cancer accounting for approximately 60,000 new cases every year in Germany. However, it is only the third common cause of death from cancer. The widespread use of PSA as screening method for prostate cancer has led to an increased incidence of prostate cancer which is accompanied by a shift towards earlier stages of detected cancers. With respect to the demographic changes in industrialized countries the incidence of prostate cancer will continue to increase.
The aim of the present trial is to demonstrate the superiority of a delayed risk-adapted screening beginning at age 50 (study arm B) as compared to a risk-adapted PSA screening beginning at age 45 with respect to the specificity of the screening.

Who can participate?
Healthy male volunteers aged 45 at the time of entering the study, with no history of prostate cancer.

What does the study involve?
Participants will be randomly allocated to receive their initial prostate cancer screening blood test, called a prostate-specific antigen (PSA) test at age 45 or age 60. Participants will be followed up and provide samples at two or five yearly intervals depending on the results of the screening.

What are the possible benefits and risks of participating?
Benefits are the delay of the start of a screening program with reduction of worries, unnecessary diagnostics like biopsies without harm because the detection of cancers 5 years later is not expected to lead to any risk.
The risk of the participation is to be randomized to the deferred PSA screening arm with a potentially late diagnosis of aggressive prostate cancer.

Where is the study run from?
1. University Hospital Dusseldorf, Germany
2. Hannover Medical School, Germany
3. Heidelberg University Hospital, Germany
4. Technical University of Munich, Germany

When is the study starting and how long is it expected to run for?
February 2014 to April 2034

Who is funding the study?
Deutsche Krebshilfe (German Cancer Aid)

Who is the main contact?
Prof. Dr. Peter Albers
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Study information

Scientific Title
Risk-adapted prostate cancer (PCa) early detection study based on a “baseline” PSA value in young men – a prospective multicenter randomized trial (PROBASE)

Acronym
PROBASE

Study objectives
Men undergoing a risk-adapted PSA screening at age 50 years do not more frequently develop metastatic disease up to the age of 60 years as compared to those men beginning a risk-adapted PSA screening at age 45 years

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 11/07/2013, Ethics committee at University Hospital Dusseldorf (40204 Düsseldorf, Germany; +49 (0)211 8119591; Ethikkommission@med.uni-duesseldorf.de), ref: 4257
2. Approved 25/09/2013, Ethics committee at Hannover Medical School (30623 Hannover, Germany; ; no tel. provided; Ethikkommission@mh-hannover.de), ref: 1989-2013
3. Approved 12/08/2013, Ethics committee at University Hospital Heidelberg (Alte Glockengießerei11/1, 69115 Heidelberg, Germany; no tel. provided; Ethikkommission-l@med.uni-heidelberg.de), ref: S-425/2013
4. Approved 16/09/2013, Ethics committee at Technical University of Munich (Ismaninger Staße 22, 81675 München, Germany; no tel. provided; Info@ek.med.tum.de), ref: 5911/13

Study design
Prospective multicenter randomized cohort study

Primary study design
Interventional

Study type(s)
Screening

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

Interventions
Men at age 45 years are randomized into two screening groups following a 1:1 distribution for early first PSA (prostate specific antigen) testing at age 45 years (study arm A) versus delayed first PSA testing at age 50 years (study arm B). To balance group sizes and to minimize selection bias between study sites a permuted-block randomization will be used. No stratification is designated.

According to the individual level of the baseline PSA value subjects of both screening groups will be submitted to the same risk-adapted screening intervals.

Subjects with a baseline PSA value <1.5 ng/ml undergo 5-yearly screening intervals as long as the PSA value remains <1.5 ng/ml in the following screening rounds.

Subjects with a baseline PSA value of 1.5-2.99 ng/ml undergo 2-yearly screening intervals.

Subjects having or exceeding the cut-off PSA value of 3.0 ng/ml at baseline or in one of the following screening rounds will be submitted to a multiparametric magnetic resonance imaging (MRI) and to a stereotactically-guided targeted biopsy combined with a random biopsy of the prostate.

Complete recruitment of the study will be finished within 5 years. Thus, the whole study duration including 15 years of screening and follow-up is estimated to be 20 years (without data cleaning and write up).

Intervention Type
Other

Primary outcome(s)
Incidence of metastatic prostate cancer up to the age of 60 years as judged by imaging and confirmatory biopsy of metastases

Key secondary outcome(s))
Measured by patient records:
1. Incidence of late metastasis (M+ = radiographically and histologically proven bone metastases and/or radiographically and histologically proven nonregional lymph node or visceral metastases) after curative treatment (radical prostatectomy, radiotherapy) of detected prostate cancers up to the age of 60 years
2. Incidence of biochemical recurrences after curative treatment (radical prostatectomy, radiotherapy) of detected prostate cancers up to the age of 60 years
3. Locally advanced prostate cancers detected up to the age of 60 years
4. Incidence of high-grade prostate cancers detected up to the age of 60 years
5. The prostate cancer mortality rate up to the age of 60 years
6. Overall survival up to the age of 60 years

Completion date
30/04/2034

Eligibility

Key inclusion criteria
1. Males at age 45 years at the time of consent
2. Willing and able to provide written informed consent
3. Written data protection consent has been obtained
4. Able to adhere to the study visit schedule and requirements of the protocol

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
45 years

Upper age limit
100 years

Sex
Male

Total final enrolment
0

Key exclusion criteria
Previous history of prostate cancer

Date of first enrolment
01/02/2014

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Dusseldorf
Department of Urology
Moorenstr. 5
Düsseldorf
Germany
40225

Study participating centre
Hannover Medical School
Department of Urology
Carl-Neuberg-Str. 1
Hannover
Germany
30625

Study participating centre
Heidelberg University Hospital
Department of Radiation Oncology
Im Neuenheimer Feld 110
Heidelberg
Germany
69120

Study participating centre
Technical University of Munich
Department of Urology
Ismaninger Str. 22
Munich
Germany
81675

Sponsor information

Organisation
German Cancer Aid

ROR
https://ror.org/01wxdd722

Funder(s)

Funder type
Charity

Funder Name
Deutsche Krebshilfe

Alternative Name(s)
Stiftung Deutsche Krebshilfe, German Cancer Aid

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2023	12/11/2024	Yes	No
Interim results article		18/10/2023	23/10/2023	Yes	No
Interim results article		01/06/2022	12/11/2024	Yes	No
Interim results article		01/03/2024	12/11/2024	Yes	No
Other publications	Worry about prostate cancer and risk perception	05/03/2025	19/05/2025	Yes	No
Other publications	Prostate Cancer Detection in Younger Men: A Comparative Analysis of Systematic and Magnetic Resonance Imaging-targeted Biopsy in the PROBASE Trial	02/06/2025	04/06/2025	Yes	No
Other publications		10/11/2025	18/11/2025	Yes	No
Study website		11/11/2025	11/11/2025	No	Yes