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Early vs. delayed screening for prostate cancer

Submission date	Recruitment status	[_] Prospectively registered
13/01/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/01/2020	Ongoing	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/06/2025	Cancer	

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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Study website
http://www.probase.de/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

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

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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

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

Interventions
Men at age 45 are randomized into two screening groups following a 1:1 distribution for early first PSA (prostate specific antigen) testing at age 45 (study arm A) versus delayed first PSA testing at age 50 (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 measure
Incidence of metastatic prostate cancer up to the age of 60 as judged by imaging and confirmatory biopsy of metastases.

Secondary outcome measures
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
2. Incidence of biochemical recurrences after curative treatment (radical prostatectomy, radiotherapy) of detected prostate cancers up to the age of 60
3. Locally advanced prostate cancers detected up to the age of 60
4. Incidence of high-grade prostate cancers detected up to the age of 60
5. The prostate cancer mortality rate up to the age of 60
6. Overall survival up to the age of 60

Overall study start date
01/01/2013

Completion date
30/04/2034

Eligibility

Key inclusion criteria
1. Males at age 45 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

Age group
Adult

Lower age limit
45 Years

Sex
Male

Target number of participants
46,000

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
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69120

Study participating centre
Technical University of Munich
Department of Urology
Ismaninger Str. 22
Munich
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Sponsor information

Organisation
German Cancer Aid

Sponsor details
Postfach 1467
Bonn
Germany
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Sponsor type
Charity

Website
http://www.krebshilfe.de/metanavigation/english.html

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

Publication and dissemination plan
Intend to publish main results and conclusions of the study.
Dissemination at congresses.
Relevant publications and magazines in public health and urology.

Intention to publish date
31/05/2020

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?
Interim results article		18/10/2023	23/10/2023	Yes	No
Interim results article		01/06/2022	12/11/2024	Yes	No
Interim results		01/03	12/11	Yes	No

article		/2024	/2024		
Results article		01/12/2023	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